

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA

JIM CHAPMAN, Individually and On
Behalf of All Others Similarly Situated,

Plaintiff,

v.

FENNEC PHARMACEUTICALS INC.,
ROSTISLAV RAYKOV, ROBERT
ANDRADE, CHRIS A. RALLIS, MARCO
BRUGHERA, ADRIAN J. HAIGH,
KHALID ISLAM, and JODI COOK,

Defendants.

Case No. 1:20-cv-00812-UA-JLW

CLASS ACTION

DEMAND FOR JURY TRIAL

**CONSOLIDATED AMENDED CLASS
ACTION COMPLAINT FOR
VIOLATIONS OF THE FEDERAL
SECURITIES LAWS**

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Lead Plaintiff Daniel Malakoti (“Lead Plaintiff” or “Mr. Malakoti”), by and through his attorneys, individually and on behalf of all others similarly situated, alleges the following based upon personal knowledge as to his own acts and on information and belief as to all other matters. Lead Plaintiff bases this information and belief on, among other things, the investigation conducted by his counsel, which includes a review and analysis of: United States Securities and Exchange Commission (“SEC”) filings by Fennec Pharmaceuticals Inc. (“Fennec” or the “Company”); press releases, analyst reports, public statements, news articles and other publications disseminated by or concerning Fennec; independent factual sources, including individuals formerly employed by the Company and related third-party companies; and other publicly available information. Counsel’s investigation into the matters alleged herein is ongoing and many relevant facts are known only to Defendants or are exclusively within their custody or control. Lead Plaintiff’s investigation indicates substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class (“Class”) consisting of all persons and entities that purchased or otherwise acquired Fennec securities between December 20, 2018 and August 10, 2020, inclusive (the “Class Period”), against Fennec, and corporate insiders Rostislav Raykov (“Raykov”), Robert Andrade (“Andrade”), Chris A. Rallis (“Rallis”), Marco Brughera (“Brughera”), Adrian J. Haigh (“Haigh”), Khalid Islam (“Islam”), and Jodi Cook (“Cook”) (collectively, “Individual Defendants”) (together with Fennec, “Defendants”), pursuing remedies under §§ 10(b) and

20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”), and SEC Rule 10b-5 promulgated thereunder. These claims are asserted against Defendants who, during the Class Period, participated in the drafting, preparation, and/or approval of the various public reports and other communications and filings with the SEC and were aware of, or recklessly disregarded, the misstatements contained therein and omissions therefrom, and were aware of their materially false and misleading nature, employed devices, schemes, and artifices to defraud, and engaged in acts, practices, and a course of conduct that operated as a fraud or deceit upon Mr. Malakoti and other members of the Class.

2. In particular, Defendants misled investors concerning Fennec’s ability to achieve approval from the United States Food and Drug Administration (“FDA”) for its New Drug Application (“NDA”) for PEDMARK™ (“PEDMARK” or the “Drug”) by knowingly failing to disclose material deficiencies related to its third-party drug manufacturers, which resulted in: (1) a March 2019 delay of the NDA submission and commercial launch because of a necessary drug *substance* manufacturing site change; and (2) the August 2020 denial of the NDA by the FDA and another delay in the commercial launch due to manufacturing deficiencies at the drug *product* manufacturing facility.¹

3. Specifically, Fennec is a biopharmaceutical company solely focused on the development of PEDMARK, a unique formulation of Sodium Thiosulfate (“STS”) for the prevention of ototoxicity (ear poisoning) induced by cisplatin chemotherapy in pediatric

¹ A drug substance consists of the raw drug materials that are required to be mixed with other components to make a drug; drug production, on the other hand, refers to the finished product of a drug that is available in the market and is ready for use.

patients with localized, non-metastatic, solid tumors.

4. On the first day of the Class Period, December 20, 2018, Fennec issued a press release announcing that it had initiated a rolling NDA to the FDA for PEDMARK and was “targeting *U.S. approval of PEDMARKTM in the second half of 2019.*”² Fennec did not manufacture PEDMARK itself, and it did not disclose to investors which third-party manufacturer it was using to manufacture its drug.

5. Subsequent investigation has revealed that, at the time of its December 2018 press release, Fennec was using Avista Pharma Solutions, Inc. (“Avista”) to manufacture the drug substance for PEDMARK. None of Avista’s facilities has ever been capable of large-scale commercial drug manufacturing. However, pursuant to FDA requirements, in order to receive approval, an NDA must provide detailed information about the manufacturer’s standard and practices, including long-term manufacturing stability data (up to six months), from the facility manufacturing PEDMARK for commercial use. Thus, Fennec knew or should have known that it would have to manufacture PEDMARK for commercial use at yet *another* site. As such, Fennec did not have the necessary stability data at the time it initiated its rolling submission of the PEDMARK NDA nor did Fennec know when it would be able to obtain such data because Avista was in the process of being acquired by Cambrex Corporation (“Cambrex”), who announced the deal in November 2018. In short, while Fennec told investors that it was targeting the “second half of 2019” for approval of PEDMARK, it did not have, nor could it have had, a reasonable basis for

² Unless otherwise noted, internal citations are omitted and emphasis is added throughout.

this publicly announced target due to its use of Avista as its drug substance manufacturer.

6. On March 13, 2019, before the markets opened, Fennec revealed to investors in a press release that “the drug substance manufacturer for PEDMARKTM was recently acquired requiring a site transition for the commercial manufacturing site.” This would delay the full submission of the PEDMARK NDA to the FDA by at least six months and the commercial launch by at least a year. Even though Fennec was now “expect[ing] a first *commercial launch for PEDMARKTM in the second half of 2020*,” it assured investors that “[t]he *new facility* of the acquiring company *has large scale commercial capabilities and a proven and extensive track record of successful FDA inspections and product launches*.” On this news of the lengthy delay, which would obviously impact the Company’s projected sales, the Company’s stock price fell over 14% to close at \$5.83 on March 14, 2019, after two days of heavy trading.

7. Fennec did not tell investors then (and still has not) what company was manufacturing PEDMARK. Nonetheless, rather than letting investors conduct their own due diligence by releasing the name of this new manufacturer or any other manufacturer, from March 13, 2019 through to the end of the Class Period, Defendants secreted that information and continued to mislead investors about the strength of their ability to manufacture PEDMARK. Fennec told investors that there would be no other manufacturing-related delays as Fennec transitioned “to becoming a commercial-stage organization” by, *inter alia*, confirming that its mysterious manufacturers had “*successfully* manufactured PEDMARK.” And Fennec assured investors that they were “*well underway* with commercialization readiness activities” and had “*made solid*

progress in ... the preparation and execution of [the Company's] commercial readiness plan" for the commercial launch of PEDMARK. Such activities and preparations included "working closely with the FDA" to obtain regulatory approval and ensuring the successful manufacturing of PEDMARK for commercial use so that it gets "to patients in need as quickly as possible" upon approval.

8. These statements made by Fennec were false. The Company's third-party drug product manufacturing facility did not, in fact, comply with current Good Manufacturing Practices ("cGMP") and those deficiencies resulted in the issuance of a Form 483 from the FDA, which is sent to facility management at the conclusion of an inspection when an FDA investigator has observed conditions that may constitute violations of the Food, Drug & Cosmetic Act (the "FDCA"). In short, manufacturing deficiencies prevented FDA approval of PEDMARK and caused yet another commercial launch delay. Compounding the issue was the fact that investors had no visibility into who Fennec had contracted with to manufacture PEDMARK and whether the manufacturer(s) had prior FDA inspection issues. The *only* information available to investors during the Class Period was Defendants' misleading positive statements about the Company's manufacturing success and preparedness for commercialization. As a result, Fennec's stock continued to trade at artificially inflated levels throughout the Class Period.

9. While Fennec stock was trading at an all-time high in anticipation of FDA approval, the Company issued a press release before the markets opened on August 11, 2020, announcing that it had received a Complete Response Letter ("CRL") from the FDA

the day before.³ Instead of FDA approval, the press release stated that “after recent completion of a pre-approval inspection of the manufacturing facility of our drug product manufacturer, the FDA identified deficiencies resulting in a Form 483, which is a list of conditions or practices that are required to be resolved prior to the approval of PEDMARK™.” Plainly stated, Fennec’s manufacturer had failed inspection, and approval of PEDMARK would be delayed. On this news, the Company’s stock price plummeted over **44%** to close at \$5.67 on August 13, 2020, after three days of heavy trading.

10. Since then, the Company has continued its obfuscation. While the Company has participated in meetings with the FDA to discuss a path forward for resubmitting the NDA, and has spent \$1.4 million in Research and Development (“R&D”) (an increase of \$573,000 over the same period in 2019, which the Company attributed to increased activities “after the CRL from the FDA related to manufacturing and regulatory”), Fennec has failed to provide any more detail to investors on when to expect resubmission; it has also not announced a new target date for the commercial launch of PEDMARK.

11. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of Fennec securities, Mr. Malakoti and the other members of the Class have suffered significant losses and damages.

II. JURISDICTION AND VENUE

12. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by

³ A Complete Response Letter (CRL) is sent by the FDA to a pharmaceutical company if the agency determines that it will not approve the company’s NDA in its present form.

the SEC (17 C.F.R. § 240.10b-5).

13. This Court has jurisdiction over the subject matter of this Action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

14. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, the Company's principal executive offices are located in this District.

15. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

16. Lead Plaintiff Daniel Malakoti was appointed to serve as Lead Plaintiff in this Action by Order of this Court dated December 3, 2020 (ECF No. 25). As set forth in his shareholder certification (ECF No. 19-1), which is incorporated by reference herein, Mr. Malakoti purchased Fennec securities at artificially inflated prices during the Class Period and suffered economic losses when true facts about the Company's business operations and future prospects were disclosed and the artificial inflation was removed from the price of Fennec securities.

17. Defendant Fennec, incorporated under the laws of British Columbia, Canada,

has its principal executive offices in Research Triangle Park, North Carolina. Fennec's common stock trades on the NASDAQ exchange under the symbol "FENC."

18. Defendant Raykov was, at all relevant times, a director and Fennec's Chief Executive Officer ("CEO"). Prior to Fennec, he was the co-founder and portfolio manager for Alchem Investment Partners ("Alchem"), an event driven hedge fund, and DCML LLC ("DCML"), a private investment partnership. Prior to founding Alchem and DCML, he was a portfolio manager and securities analyst for John A. Levin & Co., an event driven fund (2002-2005), a securities analyst for the Merger Fund at Tiedemann Investment Group (1999-2002), and an investment banking analyst at Bear Stearns (1998-1999). Mr. Raykov earned a B.S. in Business Administration from the University of North Carolina at Chapel Hill. Due to Mr. Raykov's financial expertise and experience with the Company as it has developed within the drug development industry, Fennec's SEC filings tout that he is able to provide the Company with unique insight and guidance.

19. Defendant Andrade was, at all relevant times, Fennec's Chief Financial Officer ("CFO"). Prior to Fennec, he was the co-founder and General Partner at DCML. Prior to founding DCML, he was a portfolio manager and securities analyst for Millennium Partners L.P. (2006-2007), a securities analyst for the event driven fund at Caxton Associates, LLC (2003-2005), a private equity associate at Trimaran Capital Partners (2000-2003), and an investment banking analyst at Bear Stearns (1997-1999). Mr. Andrade earned an M.A. and B.A. in Economics from the University of Southern California.

20. Defendant Islam, at all relevant times, was the Chairman of Fennec's Board of Directors ("Board"), and a member of its Audit Committee. Previously, as CEO and

Chairman of Gentium S.p.A. (“Gentium”) (2009-2014), he led its transition from a loss-making company to be cash-flow positive and profitable, increasing its value from \$25 million to a successful all cash \$1 billion merger with Jazz Pharmaceuticals, PLC (“Jazz”). Since the sale of Gentium, he has been involved on both an advisory and Board level in several public and private healthcare related companies. He is Board Chair of Minoryx Therapeutics (Spain) and Gain Therapeutics (Switzerland), and on the boards of Karolinska Development (Sweden), OxThera (Sweden), MolMed S.p.A. (Italy), and Immunomedics Inc. (IMMU). In the past, he has served as Board Chairman of Pcovery Aps (Copenhagen), Adenium Aps (Copenhagen), and C10 Pharma AS (Oslo). He was also President and CEO of Arpida AG, from 1999 to 2008, during which time he transitioned it from an early-stage start-up to a SWX-listed company and raised \$300 million in an initial public offering and follow-ons. Prior to Arpida AG, he held various positions in HMR & MMD (now Sanofi-Aventis) (1987-1999), worked in academia at Imperial College (University of London) and Milan University (1977-1987), and is a founder/co-founder of Sirius Healthcare Partners GmbH (Zurich), PrevAbr LLC (D.C.), BioAim LLC (L.A.), and Life Sciences Management GmbH (Zug). He holds several patents, has published over 80 articles in leading journals, is an advisor to the venture group Kurma Biofund in Paris, is a graduate of Chelsea College and received his Ph.D. from Imperial College, University of London. Fennec touts in its SEC filings that Dr. Islam’s extensive international pharmaceutical expertise in transitioning companies from development to production strengthened the Board’s collective qualifications, skills and experience.

21. Defendant Rallis, at all relevant times, was a director of Fennec and a

member of its Audit and Compensation Committees. In addition, he has been an executive-in-residence at Pappas Capital, a life science venture capital firm since January 2008, was the President and CEO of ImmunoBiosciences, Inc. (“IBI”), a vaccine technology company, from April 2006 to June 2007, and previously served as a consultant for Duke University and Panacos Pharmaceuticals, Inc. He also previously served as Executive Vice President (“EVP”), Business Development and General Counsel before being promoted to President, Chief Operating Officer (“COO”) and Director of Triangle Pharmaceuticals, Inc. (“Triangle”) prior to its acquisition by Gilead Sciences in 2003. While at Triangle, he participated in 11 equity financings, generating gross proceeds of approximately \$500 million, and was primarily responsible for all business development activities, which included a worldwide alliance with Abbott Laboratories and the in-licensing of ten compounds. Before joining Triangle in 1995, he served in various business development and legal management roles with Burroughs Wellcome Co., including Vice President (“VP”) of Strategic Planning and Business Development, and served on the boards of biopharmaceutical companies, Aeolus Pharmaceuticals and Tenax Therapeutics, Inc. Mr. Rallis received his A.B. degree in Economics from Harvard College and a J.D. from Duke University. As touted in Fennec’s SEC filings, as a result of his professional achievements, Mr. Rallis possessed particular healthcare industry knowledge and expertise which strengthened the Board’s collective qualifications, skills, and experience.

22. Defendant Brughera, at all relevant times, was a director of Fennec and serves as a member of its Compensation Committee. In addition, since January 2011, he has been CEO of Lediand Biosciences S.p.A. and has held several positions for the Sigma-

Tau Group, including CEO, Global Head of Sigma Tau Rare Disease, and President of Sigma-Tau Research and Sigma-Tau Pharmaceuticals. He drove the commercial revival of a lead oncology product line leading to its successful sale for around \$900M and successfully out-licensed the Defibrotide U.S. rights to Jazz. From 2004 to 2010, he served as VP of Preclinical Development at Nerviano Medical Sciences (“NMS”), a pharmaceutical oncology-focused integrated discovery and development company, and as the Managing Director at Accelera, an independent contract research organization with the NMS Group. Previously, he held senior level positions in research and development with Pharmacia and Pfizer (1999-2004) and various positions at Pharmacia & Upjohn and Farmitalia Carlo Erba SpA, an Italian pharmaceutical company (pre-1999). He currently serves on the Board of Solgenix and Lee’s Pharmaceutical, and until early 2014, the Board of Gentium SpA. Dr. Brughera earned his degree in veterinary medicine from the University of Milan and is a European Registered Toxicologist. Fennec touts in its SEC filings that, Defendant Brughera’s wide-spread experience and knowledge of pharmaceutical drug development, specifically in international companies, deepens the Board’s collective qualifications, skills and experience.

23. Defendant Haigh, at all relevant times, was a director of Fennec and a member of its Governance Committee. In addition, he has been a director at Arch Biopartners Inc. since August 2014 and a Senior Vice President (“SVP”) and General Manager of EMEA Region and Asia Pacific at PTC Therapeutics, Inc. since September 2014. Previously, he served as SVP, Chief Commercial Operations (“CCO”) and COO of Gentium GmbH; Regional VP and CCO at Biogen Idec.; General Manager of Amgen

Nordis and Portugal; and EVP of Global Marketing and Corporate Planning at EUSA Pharma, where he led the international oncology franchise. He has also held senior commercial and marketing positions at SmithKline Beecham, Schering Plough, Organon and Novo Nordisk. Mr. Haigh received a B.A. with Honors in Economic History from Huddersfield Polytechnic, West Yorkshire, England and a Diploma in Marketing from the Institute of Marketing. Fennec touts in its SEC filings that, as a result of his professional experiences, Mr. Haigh has extensive international oncology development expertise which strengthens the Board's collective qualifications, skills and experience.

24. Defendant Cook was a director of Fennec beginning in September 2019 and serves as a member of its Compensation and Governance Committees. She currently serves as Head of Gene Therapy Strategy at PTC Therapeutics, Inc. ("PTC"), a global biopharmaceutical company focused on developing and commercializing clinically differentiated medicines for patients with rare disorders. As a founding member and COO of Agilis Biotherapeutics, a clinical-stage company focused on gene therapies for patients with rare diseases, she had led its sale to PTC. Previously, she was an Assistant Professor of Audiology and Director of the Hearing Aid Program at Mayo Clinic and has held executive positions at a number of biotech start-ups within the hearing industry. Fennec touts in its SEC filings that Dr. Cook's extensive scientific, clinical and executive business experience deepened the Board's collective qualifications, skills and experience.

25. The Individual Defendants, because of their positions with the Company, had access to non-public information about the Company's business operations and prospects, financial condition, markets, and meetings and communications with the FDA and/or third-

parties *via* access to internal corporate documents, conversations, and connections with other corporate officers and employees, attendance at management and/or Board meetings and committees thereof, and *via* reports and other information provided to them in connection therewith. Because of the Individual Defendants professional achievements, education, and relevant industry expertise, the Individual Defendants were aware of regulatory requirements and had access to industry standards and protocols. Indeed, Defendant Andrade publicly stated in April 2019 that as part of its “lean and mean” structure of three employees, the Company “*leaned heavily on its board of directors, who remain[ed] intimately involved.*”⁴

26. As such, the Individual Defendants had access to material adverse non-public information concerning Fennec’s ability to achieve approval from the FDA for its PEDMARK NDA and the quality and capabilities of its third-party drug manufacturers, as discussed in detail below. Because of their possession of such information, the Individual Defendants knew or recklessly disregarded the fact that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

27. The Individual Defendants are liable as direct participants in the wrongs complained of herein. The Individual Defendants participated in the drafting, preparation, and/or approval of the various public, shareholder, and investor reports and other communications complained of herein and were aware of, or recklessly disregarded, the

⁴ Seth Thomas Gullledge, *This \$90M public company is “set up” for sale, CFO says*, AMERICAN CITY BUSINESS JOURNALS (Apr. 25, 2019 2:30 PM EDT), <https://www.bizjournals.com/triangle/news/2019/04/25/this-90m-public-company-is-set-up-for-sale-cfo.html>.

misstatements contained therein and omissions therefrom, and were aware of their materially false and misleading nature. Each of the Individual Defendants had access to the adverse undisclosed information about Fennec's ability to achieve approval from the FDA for its PEDMARK NDA and the quality and capabilities of its third-party drug manufacturers as particularized herein, and knew or recklessly disregarded that these adverse facts rendered the positive representations made by or about Fennec and its business, which were issued or adopted by the Company, materially false and misleading.

28. In addition, the Individual Defendants, by reason of their positions with Fennec, were "controlling persons" within the meaning of § 20(a) of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to, and did, directly or indirectly, control the conduct of Fennec's business.

29. As control persons of a publicly traded company whose common stock was, and is, registered with the SEC pursuant to the Exchange Act, and was, and is, traded on the NASDAQ and governed by the federal securities laws, the Individual Defendants had a duty to promptly disseminate accurate and truthful information with respect to Fennec's financial condition and performance, growth, operations, financial statements, business, markets, management, earnings, and present and future business prospects, and to correct any previously issued statements that had become materially misleading or untrue so that the market price of Fennec's securities would be based upon truthful and accurate information. The Individual Defendants' material misrepresentations and omissions of material facts during the Class Period violated these specific requirements and obligations.

30. The Individual Defendants are liable as participants in a fraudulent scheme and course of conduct that operated as a fraud or deceit on purchasers of Fennec's publicly traded securities by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme deceived the investing public concerning the Company's ability to gain approval from the FDA for its PEDMARK NDA and the quality and capabilities of its third-party drug manufacturers, causing Lead Plaintiff and other members of the Class to purchase Fennec common stock at artificially inflated prices.

IV. SUBSTANTIVE ALLEGATIONS

A. The FDA's New Drug Application, Generally

31. Enacted in 1938, the Food, Drug and Cosmetic Act (FDCA) created the FDA, an agency of the United States Department of Health and Human Services, to "protect the public health" by ensuring that "drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B). The FDCA provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to [this section] is effective with respect to such drug." 21 U.S.C. § 355(a).

32. Accordingly, new pharmaceutical drugs, such as PEDMARK, must receive FDA approval prior to sale, marketing, and commercial distribution in the United States. Drug sponsors/applicants, such as Fennec, seek approval from the FDA through the FDA's New Drug Application (NDA) process. The NDA process has been designed to provide information to permit the FDA to determine whether: (i) the drug is safe and effective in its proposed use(s), and the benefits of the drug outweigh the risks; (ii) the drug's proposed labeling (package insert) is appropriate, and what it should contain; and (iii) the methods

used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality and purity.⁵

1. Clinical Trials

33. The NDA process includes adequate and well-controlled human clinical trials to establish the efficacy of the drug for each indication.

34. Clinical trials involve the administration of the drug to human subjects under the supervision of qualified clinical investigators.⁶ Clinical trials are conducted under protocols detailing the objectives of the study, the parameters used in monitoring safety, and the effectiveness criteria to be evaluated. Each clinical trial protocol must be submitted to the FDA for clearance. Clinical trials are typically conducted in four sequential phases:

- **Phase I** involves researchers testing an experimental drug or treatment in a small group of people for the first time. The researchers evaluate the treatment's safety, determine a safe dosage range, and identify side effects.
- **Phase II** involves the experimental drug or treatment being given to a larger group of people to see if it is effective and to further evaluate its safety.
- **Phase III** involves the experimental drug or treatment being given to large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.
- **Phase IV** involves post-marketing studies, conducted after a drug or treatment is approved for use by the FDA, which provide additional information, including the treatment or drug's risks, benefits, and best use.

⁵ U.S. FOOD & DRUG ADMIN., NEW DRUG APPLICATION (NDA) (June 10, 2019), <https://www.fda.gov/drugs/types-applications/new-drug-application-nda>.

⁶ U.S. FOOD & DRUG ADMIN., WHAT ARE THE DIFFERENT TYPES OF CLINICAL RESEARCH? (Jan. 4, 2018), <https://www.fda.gov/patients/clinical-trials-what-patients-need-know/what-are-different-types-clinical-research>.

35. Once the required clinical testing is successfully completed, the results of the preclinical and clinical studies are submitted to the FDA as part of an NDA.

2. CMC Requirements and Manufacturing Changes

36. Chemistry, Manufacturing and Controls (“CMC”) is an integral part of any pharmaceutical NDA submitted to the FDA. CMC applies to the entire product lifecycle – beginning during Phase I clinical trials, continuing through post-approval and beyond. CMC ensures that pharmaceutical drug products are consistently effective, safe and high quality for consumers. It sustains a connection between the drug that is used in clinical studies and the commercial drug that is marketed and available to consumers. CMC applies to both the drug itself and the facility in which the drug is being manufactured.

37. A sponsor or manufacturer may choose to make changes during the drug development process, such as a new manufacturing site, formulation, purification column, equipment, or components, however, when changes are made to the manufacturing process, the sponsor and/or manufacturer must demonstrate that the changes will not have an adverse impact on the quality, safety, and efficacy of the drug product.

38. For example, manufacturing changes due to a site-transfer requires additional site-specific stability data (“SSS data”). To determine the amount of SSS data needed, the potential for an adverse impact is assessed on a three-tiered risk-based system, examining the timing of the change, the drug substance makeup and the drug product form.

39. First, a manufacturing change due to site-transfer is ranked as having *major* potential to have an adverse effect on the drug substance/product stability occurs when: (i) the change is at submission (prior to the NDA filing); (ii) the form or particle size of the

drug substance is critical to the performance of the drug product; or (iii) the drug product composition consists of modified release solid oral dosage forms, sterile lyophilized powders, liposomal formulations, meter-dosed inhalers, dry-powder inhalers, or transdermal patches. The amount of SSS data needed in these circumstances could take anywhere from 3 to 12 months to produce.

40. Second, the FDA ranks manufacturing changes due to site-transfer as having *moderate* potential to have an adverse effect on the drug substance/product stability when: (i) the change occurs at a midpoint in the NDA review cycle; (ii) the drug substance is susceptible to manufacturing conditions, technology or site transfer (*e.g.* biotechnology/biological products; environmentally sensitive substances); or (iii) the drug product composition consists of solid oral dosage forms where the drug substance has low solubility, suspensions, semisolids, sterile solutions (including nasal, ophthalmic, topical solutions), sterile powders, or drug products containing drug substances susceptible to manufacturing conditions. The amount of SSS data needed in these circumstances would likely take about 3 months to produce.

41. Third, the FDA ranks manufacturing changes due to site-transfer as having *minor* potential to have an adverse effect on the drug substance/product stability when: (i) the change occurs post-approval in the Annual Report; (ii) the drug substance is any other substance not listed; or (iii) the drug product composition consists of solid oral dosage forms where the drug substance has high solubility, non-sterile solutions, powders for oral solution or suspension. Such circumstances do not call for any additional data other than the standard stability commitment.

42. In order to assemble the necessary SSS data, the sponsor and/or manufacturer must conduct a comparability or bridge study to show that drug substance and/or drug product affected by the change, when studied side-by-side in a well-controlled study, is consistent with what has been produced throughout the development program, *i.e.* clinical trials. This requires the sponsor to compare post-change product to pre-change product following manufacturing process changes; and assessing the impact of observed difference in the quality attributes caused by the manufacturing process change for a given product as it relates to safety and efficacy of the product.

43. The demonstration of comparability does not require the quality attributes of the pre-change and post-change drug product to be identical, but to be highly similar, and that the existing knowledge is sufficiently predictive to ensure that any difference in quality attributes have no adverse impact on the safety and efficacy of the drug product.

44. A determination of comparability can be based on a combination of analytical testing, assays, and in some cases, nonclinical and clinical data. If a sponsor and/or manufacturer can provide assurance of comparability through analytical studies alone, nonclinical or clinical studies with the post-change product is not required. However, where the relationship between specific quality attributes and safety and efficacy has not been established, and differences between quality attributes of the pre- and post-change product are observed, it might be appropriate to include a combination of quality, nonclinical and/or clinical studies in the comparability exercise.

3. *Pre-Submission Meeting with the FDA*

45. Prior to submitting an NDA filing, the FDA will conduct a pre-submission

meeting with the sponsor to discuss possible filing and format issues.⁷ Typically, a pre-submission meeting will be held 6 months prior to the planned NDA submission date.

46. As part of the pre-submission meeting, the CMC review team will meet with the sponsor to ensure the submission of a well-organized and complete NDA. Examples of CMC issues that could be addressed in the pre-submission meeting include, but are limited to: (i) discussion of the relationship between the manufacturing, formulation, and packaging of the drug product used in the Phase III studies and the final drug product intended for marketing, and assurance that any previously agreed upon comparability or bridging studies have been appropriately completed; (ii) assurance that the submission will contain adequate stability data in accordance with stability protocols agreed upon previously in meetings with the FDA; (iii) confirmation that all facilities (*e.g.*, manufacturing, testing, packaging) will be ready for inspection by the time of the NDA submission; and (iv) identification of any other issues, potential problems, or regulatory issues that should be brought to the attention of the FDA or sponsor.

4. NDA Submission and Special Designation

47. After successful completion of the required clinical testing, the preclinical study and clinical trial results are submitted to the FDA as part of an NDA to support approval to market a drug for one or more indications, along with detailed information regarding the drug or treatment's CMC and proposed labeling, among other things.

⁷ U.S. DEPT. OF HEALTH AND HUMAN SERVICES, GUIDANCE FOR INDUSTRY (May 2001), <https://www.fda.gov/files/Guidance-for-Industry---IND-Meetings-for-Human-Drugs-and-Biologics---Chemistry--Manufacturing--and-Controls-Information-%28PDF%29.pdf>.

48. The FDA must conduct a preliminary review of an NDA within 60 days after submission to determine whether it is sufficiently complete to permit a substantive review. If the FDA accepts the NDA for filing, it begins the substantive review process, reviewing the NDA to determine, among other things, whether the drug is safe and effective for its intended use and whether the facility in which it is manufactured, processes, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

49. Typically, the NDA review process does not begin until a drug sponsor submits a full application to the FDA. However, because expediting the availability of drugs that treat serious diseases is in the public interest, particularly when a drug is the first available treatment or has advantages over existing treatments, the FDA developed four distinct approaches to making such drugs available as quickly as possible: (i) Priority Review; (ii) Breakthrough Therapy; (iii) Accelerated Approval; and (iv) Fast Track.⁸

50. In 1992, under the Prescription Drug User Fee Act ("PDUFA"), the FDA agreed to specific goals for improving the drug review time and created a two-tiered system of review times – Standard Review and Priority Review.⁹ A Priority Review designation means the FDA's goal is to take action on an application within 6 months (versus 10 months for standard review). A Priority Review designation is reserved for applications of drugs

⁸ U.S. FOOD & DRUG ADMIN., FAST TRACK, BREAKTHROUGH THERAPY, ACCELERATED APPROVAL, PRIORITY REVIEW (Feb. 23, 2018), <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review>.

⁹ U.S. FOOD & DRUG ADMIN., PRIORITY REVIEW (Jan. 4, 2018), <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review>.

that, if approved, would significantly improve the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.

51. Fast Track is specifically designed to facilitate the development, and expedite the review, of drugs treating serious conditions and filling an unmet medical need in order to get them to patients earlier.¹⁰ A drug that receives Fast Track designation is eligible for, among other things: Accelerated Approval and Priority Review if certain criteria are met, and a Rolling Review, meaning that a drug sponsor can submit sections of its NDA for review as they are completed rather than waiting for all sections to be completed. The FDA informs a sponsor of a Priority Review designation within 60 days of receiving an NDA.

52. Similarly, Breakthrough Therapy is designed to expedite the development and review of drugs intended to treat a serious condition and whose preliminary clinical evidence indicates that it may demonstrate substantial improvement over available therapy on a clinically significant endpoint.¹¹ For this designation, a clinically significant endpoint generally is one that measures an effect on irreversible morbidity or mortality, or on symptoms that represent serious consequences of the disease. A drug that receives Breakthrough Therapy designation is eligible for all Fast Track features in addition to intensive guidance on an efficient drug development program and organizational commitment involving FDA senior managers.

¹⁰ U.S. FOOD & DRUG ADMIN., FAST TRACK (Jan. 4, 2018), <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track>.

¹¹ U.S. FOOD & DRUG ADMIN., BREAKTHROUGH THERAPY (Jan. 4, 2018), <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy>.

5. *NDA Review – Pre-Approval Inspection*

53. As part of the NDA process, a drug sponsor must provide the FDA with sufficient information to reach a decision as to “[w]hether the methods used in manufacturing the drug and the controls used to maintain the *drug’s quality* are adequate to preserve the drug’s identity, strength, quality, and purity.” 505(b)(1)(D), 21 C.F.R. § 314.50(d)(1)(i).

54. The FDA ensures a drug’s quality by monitoring the drug manufacturer(s)’ compliance with the FDA’s Current Good Manufacturing Practice (cGMP) regulations. The cGMP regulations contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug to ensure that it is safe for use and has the ingredients and strength it claims to have.

55. As such, the NDA review process includes an examination of the drug manufacturer’s compliance with the cGMP regulations and a determination of whether it has the necessary facilities, equipment, and ability to manufacture the drug. To assist in that determination, the FDA performs a pre-approval inspection (“PAI”).¹² The FDA conducts both domestic and international PAIs for generic and innovator drug applications, and may inspect all facilities associated with a submission, including drug component manufacturing (such as Active Pharmaceutical Ingredients (“APIs”), also known as drug substances), finished drug product manufacturing, and control testing laboratories.¹³

¹² Denise DiGiulio, *What To Expect When Being Inspected*, U.S. FOOD & DRUG ADMIN., (July 15-16, 2015), <https://www.fda.gov/media/92857/download>.

¹³ U.S. FOOD & DRUG ADMIN., COMPLIANCE GUIDANCE MANUAL (Apr. 12, 2010), <https://www.fda.gov/media/71498/download>.

56. Since the goal is to confirm that the manufacturer named in an NDA is capable of manufacturing the drug, and that the submitted data is accurate and complete, the FDA's three main objectives for the PAI are to: (i) assess readiness for commercial manufacturing, *i.e.* determine if the manufacturer(s) has a quality system designed to achieve sufficient control over the facility and commercial manufacturing operations; (ii) assess conformance to the application, *i.e.* verify that the formulation, manufacturing or processing methods, and analytical (or examination) methods, are consistent with descriptions in the NDA; and (iii) conduct a data integrity audit, *i.e.* audit the raw data (hardcopy or electronic) to authenticate the submitted data and verify that all relevant data was submitted such that the FDA could rely on the data as complete and accurate.

57. When conducting a PAI, trained investigators tour the facility with the facility's staff and the drug sponsor, look for significant deviations from the FDCA and other acts where the FDA has enforcement authority, and take note of factual observations that, in their judgment, constitute violations of FDA standards. Any reportable inspection observations are presented and explained to the facility's management and the drug sponsor at an exit interview on the last day of the inspection, and then recorded in a Form 483 (explained below) issued to the facility after the exit interview. FDA Investigators and analysts make every reasonable effort to discuss all observations with facility management and the drug sponsor as they are observed or on a daily basis, to minimize surprises, errors and misunderstandings when the Form 483 is issued.

58. Reportable inspection observations warranting a Form 483 include:

- PAI findings reflect differences from the filed CMC ("Chemistry and

Manufacturing Controls”) description for bio-batch, or stability batches, such that the proposed commercial batch record does not assure a reproducible manufacturing operation.

- PAI lists differences from filed CMC description of formulations, processing principles, equipment use, or discrepancies in raw material lot reconciliation (*i.e.* inconsistencies in records for receipt, inventory, or use in production).
- Missing or unreliable data in that the data/information submitted was potentially unreliable or misleading or there were unexplained or inappropriate gaps in a chromatographic or analytical sequence.
- A pattern of inappropriately disregarded test results and/or inadequate or lack of justification for not reporting data/information.
- Insufficiency, discrepancy, or failing of an analytical method validation program.
- Lack of suitability of the facility, equipment or manufacturing operations intended for making the commercial API or finished product to the cGMP regulations.
- Other specific non-conformance (*e.g.*, conditions, practices, procedures) with the cGMP regulations.

59. All observations recorded in a Form 483 are significant and correlate to regulated products or processes being inspected. Notations may be made for recurring or not corrected observations (*i.e.* a “repeat observation”), but not required. Facility management has fifteen days to provide written responses to the Form 483 observations.

60. If the FDA does not approve an NDA, it will send the sponsor a Complete Response Letter (CRL).¹⁴ The CRL describes all the specific deficiencies that the FDA identified in the NDA and when possible, recommends actions that the sponsor could take

¹⁴ Applications for FDA Approval to Market a New Drug, Complete Response Letter to Applicant, 21 C.F.R. § 314.110 (2020), <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.110>.

to place its NDA in condition for approval. A sponsor may resubmit its NDA clearly stating that it considers the resubmission a complete response to the deficiencies outlined in the CRL that needed to be addressed by the sponsor prior to approval of the original NDA.¹⁵ Upon receipt of a resubmission, the FDA will determine whether or not the response is a complete response; if so, an acknowledgement of receipt letter will be issued stating the classification of the resubmission, Class 1 or Class 2, and the performance goal date.¹⁶

61. Pursuant to PDUFA, the FDA is committed to reviewing and acting on a sponsor's resubmission in six months or less. Any resubmission constitutes the start of a new review cycle beginning on the date the FDA receives the resubmission; the cycle is two months for a Class 1 resubmission and six months for a Class 2 resubmission. This classification is based on the information submitted by the sponsor in response to the CRL. A Class 1 resubmission includes the following items (or combination of these items):

- Final printed labeling.
- Draft labeling.
- Safety updates submitted in the same format, including tabulations, as the original submission with new data and changes highlighted (but if the resubmission presents a large amount of new information, including important new adverse experiences, it will be a Class 2 resubmission).
- Stability updates to support provisional or final dating periods.
- Assay validation data.

¹⁵ CENTER FOR DRUG EVALUATION AND RESEARCH, MANUAL OF POLICY AND PROCEDURES (effective date Feb. 26, 2015), <https://www.fda.gov/media/72727/download>.

¹⁶ The Class 1 or Class 2 distinction does not pertain to resubmissions of non-efficacy supplements (*i.e.* labeling and manufacturing supplements). *See* n.15.

- Discussions of post-marketing requirement/commitments, including proposals or protocols for such requirements/commitments (*i.e.* Phase IV).
- Final release testing on the last 1-2 lots used to support approval.
- A minor re-analysis of data previously submitted to the application (determined by the FDA as fitting the Class 1 category).
- Other minor clarifying information determined by the FDA as fitting the Class 1 category.
- Other specific items identified by the FDA and communicated through guidance for industry.

A Class 2 resubmission includes any item not specified as a Class 1 item, including any item that would warrant presentation to an advisory committee or a re-inspection.

B. Fennec and the Development of PEDMARK

62. Fennec is a biopharmaceutical company focused primarily on developing PEDMARK, a unique formulation of Sodium Thiosulfate (STS) for the prevention of ototoxicity, *i.e.* hearing loss, induced by cisplatin chemotherapy in pediatric patients with localized, non-metastatic, solid tumors. Cisplatin and other platinum compounds are key chemotherapeutic components for many pediatric malignancies, but platinum-based therapies can cause ototoxicity, and are particularly harmful to pediatric cancer survivors.

63. In November 2002, Fennec acquired an exclusive worldwide license agreement with Oregon Health & Science University (“OHSU”) for the intellectual property directed to thiol-based compounds including STS and their use in oncology. In addition to preclinical studies, OHSU investigators completed Phase I and Phase II studies showing that STS reduces the hearing loss associated with platinum-based chemotherapy.

64. The FDA granted PEDMARK Orphan Drug Designation in 2004.¹⁷ The Orphan Drug Act provides for granting special status to a drug or biological product to treat a rare disease or condition, but that status does not alter the standard regulatory requirements and process for obtaining marketing approval.¹⁸ The drug's effectiveness and safety still must be established through adequate and well-controlled studies.

65. Through collaborative partnerships, Fennec provided PEDMARK for two Phase III clinical studies. First, between June 23, 2008 and September 28, 2012, the Clinical Oncology Group Protocol ("COG") ACCL0431 enrolled 131 participants from 38 institutions. The COG ACCL0431 study included one of five childhood cancers typically treated with intensive cisplatin therapy for localized and disseminated disease, including hepatoblastoma, germ cell tumor, osteosarcoma, neuroblastoma, and medulloblastoma. COG ACCL0431 final results were published in the Lancet Oncology in December 2016.

66. Second, the International Childhood Liver Tumor Strategy Group, also known as SIOPEL, launched SIOPEL 6, a multi-center open label randomized Phase III trial enrolling hepatoblastoma patients with localized tumors.¹⁹ From October 2007 to

¹⁷ *Fennec Announces Issuance of U.S. Patent for PEDMARK™*, FENNEC PHARMACEUTICALS, INC. (Sept. 21, 2020 6:00 AM ET), <https://www.globenewswire.com/news-release/2020/09/21/2096346/0/en/Fennec-Announces-Issuance-of-U-S-Patent-for-PEDMARK.html>.

¹⁸ U.S. FOOD & DRUG ADMIN., DESIGNATING AN ORPHAN PRODUCT: DRUGS AND BIOLOGICAL PRODUCTS (Apr. 6, 2020), <https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products>.

¹⁹ *Fennec Announces Preliminary Results of SIOPEL 6 Study on PEDMARK™ (sodium thiosulfate) to be Presented at the 49TH Congress of the International Society of*

December 2014, 52 centers in 11 countries worldwide enrolled 113 evaluable patients. In February 2015, the Independent Data Monitoring Committee (“IDMC”), established to assess any potential concern of adverse effect of STS on the efficacy of the cisplatin chemotherapy and to review safety according to protocol pre-specified patient numbers, recommended the continuation of SIOPEL 6 to allow for a final safety review on 100 patients. The IDMC completed its review in October 2017. The final results of the SIOPEL 6 study were published in the June 21, 2018 issue of the New England Journal of Medicine.

67. Under the terms of its agreement with both COG and SIOPEL, Fennec had to provide the drug, drug distribution and pharmacovigilance, or safety monitoring, for the studies. Pursuant to Fennec’s agreement with SIOPEL, preparations of sodium thiosulfate, *i.e.* the drug substance, was made by American Regent, Inc., and the packaging and labeling, *i.e.* the drug product, was completed by Almac Clinical Services Ltd.²⁰

68. On October 16, 2017, Fennec announced the SIOPEL 6 study had met its primary endpoint, concluding that the randomized Phase III trial showed that adding STS significantly reduced the incidence of cisplatin-induced hearing loss without any evidence of tumor protection, and discussed its plan to pursue FDA approval of PEDMARK based

Pediatric Oncology (SIOP) 2017 Meeting, FENNEC PHARMACEUTICALS, INC. (Sept. 13, 2017 12:16 PM ET), <https://www.globenewswire.com/news-release/2017/09/13/1120427/0/en/Fennec-Announces-Preliminary-Results-of-SIOPEL-6-Study-on-PEDMARK-sodium-thiosulfate-to-be-Presented-at-the-49TH-Congress-of-the-International-Society-of-Pediatric-Oncology-SIOP-20.html>.

²⁰*SIPOEL 6 - Standard Risk Hepatoblastoma*, INTERNATIONAL SOCIETY OF PEDIATRIC ONCOLOGY (Oct. 31, 2007), https://www.nejm.org/doi/suppl/10.1056/NEJMoa1801109/suppl_file/nejmoa1801109_protocol.pdf.

on data from the SIOPEL 6 study and proof of principle data from COG ACCL0431.²¹

69. In March 2018, the FDA granted PEDMARK Breakthrough Therapy and Fast Track designations.²² As discussed above, Fast Track designation allowed Fennec to work closely with the review team within the FDA's Oncology Division, to submit the NDA on a rolling basis, and to receive Priority Review when the NDA was filed.

70. On December 20, 2018, Fennec announced that, following a pre-submission meeting with the FDA's Oncology Division, it had initiated a Rolling Review of the PEDMARK NDA, claiming a target date for FDA approval in the second half of 2019.²³

71. In March 2020, Fennec announced that the United States Patent and Trademark Office ("USPTO") will issue United States Patent 10,596,190 entitled "Method for Reducing Ototoxicity in Pediatric Patients Receiving Platinum-Based Chemotherapy," which captured the use of PEDMARK to reduce the ototoxic effects of cisplatin in pediatric

²¹ *Fennec Announces Positive Results From Phase 3 SIOPEL 6 Study on PEDMARK™ (sodium thiosulfate) Presented at the 49th Congress of the International Society of Pediatric Oncology (SIOP) 2017 Meeting*, FENNEC PHARMACEUTICALS, INC. (Oct. 16, 2017 6:00 AM ET), <https://www.globenewswire.com/news-release/2017/10/16/1147926/0/en/Fennec-Announces-Positive-Results-From-Phase-3-SIOPEL-6-Study-on-PEDMARK-sodium-thiosulfate-Presented-at-the-49th-Congress-of-the-International-Society-of-Pediatric-Oncology-SIOP-2.html>.

²² *Fennec Pharmaceuticals Receives Fast Track Designation By FDA for PEDMARK*, FENNEC PHARMACEUTICALS, INC. (Mar. 21, 2018), <https://investors.fennecpharma.com/news-releases/news-release-details/fennec-pharmaceuticals-receives-fast-track-designation-fda>.

²³ *Fennec Pharmaceuticals Initiates Rolling New Drug Application to U.S. Food and Drug Administration for PEDMARK™*, FENNEC PHARMACEUTICALS, INC. (Dec. 20, 2018 6:00 AM ET), <https://www.globenewswire.com/news-release/2018/12/20/1670128/0/en/fennec-pharmaceuticals-initiates-rolling-new-drug-application-to-u-s-food-and-drug-administration-for-pedmark.html>.

patients, particularly in the age group of five years or younger.²⁴ Application No. 16/112,195, approved and issued as Patent 10,596,190, was filed on August 24, 2018 in continuation of U.S. Application No. 15/826,243, filed on November 29, 2017.

72. Patent 10,596,190 explains STS is a water-soluble thiol compound with reducing agent properties. When detailing the “Packaging and Labeling” of STS provided by Fennec, used in the SIOPEL 6 study, Patent 10,596,190 states:

Each vial was placed into a six vial kit box. Each box was labelled with a multi-language kit label. STS drug product was manufactured, labelled, and packaged under GMP conditions and supplied as a 25% (250 mg/ML), preservative free, sterile solution. The drug product formulation contained sodium thiosulfate pentahydrate and sodium borate. The vial label indicated the drug product batch number and the initial release until date.

73. Further, Patent 10,596,190 discusses the “Preparation” as follows:

STS was supplied in 50 ml vials containing a 25% (250 mg/ml or 12.5 g/vial) solution. Each ml of the 25% STS was diluted with one ml of sterile water for injection (1:1 dilution) to a concentration of 125 mg/ml for direct administration. (This is approximately equivalent isotonicity to a 2.3% sodium chloride solution). The volume from the appropriate number of vials for the dose was combined in a PVC IV infusion bag.

Reconstituted STS for administration consisted of a clear solution. There were no preservatives in the formulation. After dilution the PVC infusion bag containing the dosing solution was placed upside down (inverted with injection and filling ports at the top) at room temperature and used within eight hours. Any solution remaining in the vial was destroyed according to institutional procedures.

74. In September 2020, Fennec announced the issuance of United States Patent 10,792,363 entitled “Anhydrous Sodium Thiosulfate and Formulations Thereof,” which

²⁴ *Fennec Announces Issuance Of U.S. Patent For Use Of PEDMARK™*, FENNEC PHARMACEUTICALS, INC. (Mar. 5, 2020), <https://investors.fennecpharma.com/news-releases/news-release-details/fennec-announces-issuance-us-patent-use-pedmarktm>.

captured the unique anhydrous form of the active ingredient in PEDMARK, and related methods of synthesis.²⁵ Patent 10,792,363 was issued in connection to Application No. 16/458,261 filed on July 1, 2019, which claimed priority to and incorporated, U.S. Provisional Patent Application Nos. 62/693,502 and 62/693,503, both filed on July 3, 2018. The application also related to and incorporated U.S. Patent Application No. 16/458,267, titled “Formulations of Anhydrous Sodium Thiosulfate” filed on July 1, 2019.²⁶

75. In addition to a sterile solution administered intravenously, as utilized in the SOIPEL 6 study and detailed in Patent 10,596,190, Patent 10,792,363 offers “[t]he STS formulation may be provided as a liquid, a suspension, or as a dry composition” and administered:

Pharmaceutical compositions suitable for administration by injection include sterile aqueous solutions, suspensions, or dispersions and sterile powders or lyophilizates for the extemporaneous preparation of sterile injectable solutions or dispersion.

Suitable methods of drying are, for example, spray drying, and lyophilization (freeze-drying). In one aspect, the STS formulation is prepared as a solution and then dried by lyophilization. In another aspect, the STS formulation is prepared as a dry composition that reconstituted immediately prior to use with sterile water for injection and then administered intravenously by either direct veni-puncture or using an intravenous line.

Suitable compositions for transdermal application include an effective amount of a biologically active agent with a suitable carrier. Carriers suitable for transdermal delivery include absorbable pharmacologically acceptable

²⁵ *Fennec Announces Issuance of U.S. Patent For PEDMARK™*, FENNEC PHARMACEUTICALS, INC. (Sept. 21, 2020), <https://fennecpharma.com/fennec-announces-issuance-of-u-s-patent-for-pedmark/>.

²⁶ While Application No. 16/458,267 is still pending, it was assigned to Fennec and Avista on August 7, 2020. See <https://patents.google.com/patent/US20200023003A1/en> (last visited on Jan. 28, 2020).

solvents to assist passage through the skin of the host.

Suitable compositions for topical application, *e.g.*, to the skin, eyes, or joints, include aqueous solutions, suspensions, ointments, creams, gels or sprayable formulations, *e.g.*, for delivery by aerosol or the like. Such topical delivery systems will in particular be appropriate for dermal application. They are thus particularly suited for use in topical, including cosmetic, formulations well known in the art. Such may contain solubilizers, stabilizers, tonicity enhancing agents, buffers, or preservatives.... [A] topical application may also pertain to an inhalation or to an intranasal application. They may be conveniently delivered in the form of a dry powder (either alone, as a mixture, for example a dry blend with lactose, or a mixed component particle, for example with phospholipids) from a dry powder inhaler or an aerosol spray presentation from a pressurized container, pump, spray, atomizer or nebulizer, with or without the use of a suitable propellant.

76. Patent 10,792,363 also discusses the possible methods of containing the STS formulation based on the various compositions mentioned above, stating in relevant part:

For liquid or suspension compositions, the container is preferably a single chamber syringe. For dry compositions, preferably the container is a dual chamber syringe. The dry composition is provided in a first chamber of the dual-chamber syringe and reconstitution solution is provided in a second chamber of the dual chamber syringe.

Prior to administering the dry STS formulation to a subject in need thereof, the dry composition is reconstituted. Reconstitution can take place in the container in which the dry STS formulation is provided, such as in a vial, syringe, dual-chamber syringe, ampoule, or cartridge. Reconstitution is performed by adding a predefined amount of reconstitution solution to the dry composition. Reconstitution solutions are sterile liquids, such as water for injection, phosphate buffered saline, isotonic saline, or other buffers, which may contain further excipients, such as preservatives and/or antimicrobials, such as, for example, benzylalcohol and cresol. Preferably, the reconstitution solution is sterile water for injection. Alternatively, the reconstitution solution is sterile phosphate buffered saline (PBS) or physiological saline.

Another embodiment is a kit comprising one or more vials or pre-filled syringes comprising a solution or suspension of one or more STS formulations. [S]uch a kit comprises a vial or pre-filled syringe comprising STS formulations as described herein in a blister pack or a sealed sleeve. The blister pack or sleeve may be sterile on the inside. In one aspect, vials or pre-

filled syringes as described herein may be placed inside such blister packs or sleeves prior to undergoing sterilization, for example terminal sterilization. The kit may also comprise documents comprising prescribing information or instructions for use.

77. Patent 10,792,363 determines “STS may be administered parenterally or enterally. If administered parenterally, the STS can be administered intravenously (IV), subcutaneously (SC), or intramuscularly (IM). Enteral administration includes oral, sublingual, or rectal.”

C. Defendants’ Fraudulent Scheme to Hide Drug Substance and Production Manufacturing Deficiencies

1. Unbeknownst to investors, Fennec’s drug substance manufacturer was not capable of manufacturing PEDMARK for commercial use, which caused a lengthy delay.

78. As stated above, in December 2018, Fennec publicly announced that it was targeting U.S. approval of PEDMARK in the second half of 2019. However, as described below, Fennec knew, or should have known, that this release date was unfeasible and unlikely when announced to investors.

79. Although Defendants have never disclosed to investors the identity of PEDMARK’s drug substance manufacturer, Plaintiff’s investigation confirms that at the time Fennec met with the FDA for its pre-submission meeting in December 2018, that manufacturer was Avista.²⁷

80. Avista, however, was not capable of manufacturing PEDMARK for commercial use. This meant that Fennec would have to transition production to another

²⁷ See Deniel Mero, *Fennec Delays NDA Due to Manufacturing Facility Change*, PROPTHINK (Mar. 13, 2019 11:48 AM), <https://proptthink.com/fennec-delays-nda-due-to-manufacturing-facility-change/#>, *infra* ¶82; and *supra* ¶74.

site for commercial manufacturing and therefore, its disclosures to investors should have taken into account the extra time needed to provide additional stability data to the FDA as part of its NDA submission

81. In that regard, at the time that Fennec told investors that it was targeting U.S approval of PEDMARK in the second half of 2019, Avista operated four facilities located in Durham, NC (“Durham Site”); Longmont, CO (“Longmont Site”); Agawam, MA; and Edinburgh, Scotland, UK.²⁸

82. None of these facilities was capable of manufacturing PEDMARK for use by consumers:

- A former Scientist who worked at the Durham Site from June 2019 to July 2020, and who was aware that PEDMARK was a compound that Cambrex was working on, confirmed that the Durham Site was an analytical site for early phase drug development, *not* a commercial manufacturing site for making finished drug product.
- A former Research Associate in Process Chemistry at the Longmont Site from June 2018 to October 2020, formerly a Manufacturing Chemist from November 2017 to June 2018, stated that the Durham Site was not capable of making drugs for Phase III or commercial scale at any level. The Research Associate further stated that after Cambrex acquired Avista, a number of drugs being manufactured at Avista facilities were transferred to Cambrex facilities, including to its largest site in Charles City, IA, because those drugs needed to be produced in a facility with a higher or different manufacturing capability and/or the client was not happy with Avista’s performance. The Research Associate noted that while neither of Avista’s two manufacturing facilities (in Longmont or Durham) were capable of making injectable doses (a requirement for PEDMARK), Avista could make a drug in powder form

²⁸ *Cambrex to Acquire Avista Pharma Solutions, Adding Early Stage API and Finished Dosage Form Development & Testing Services to its Global Contract Development & Manufacturing Network*, CAMBREX CORP. (Nov. 20, 2018), <https://www.cambrex.com/cambrex-to-acquire-avista-pharma-solutions-adding-early-stage-api-and-finished-dosage-form-development-testing-services-to-its-global-contract-development-manufacturing-network/>.

and then ship it to another manufacturer to transform the powder into injectable doses.

- A former Senior Director of Corporate Planning at the Longmont Site from July 2016 to March 2018 stated that if a pharmaceutical company changes where its drug is manufactured after the conclusion of Phase III, it would need to submit a detailed bridging study in the CMC section of the NDA about the new facility, its processes for making the drug, quality controls, and proof that everything equates to what the previous facility was doing.

83. Due to the fact that none of Avista's facilities – then or now – are capable of large-scale commercial manufacturing, at all relevant times, Fennec knew or should have known that it would have to manufacture PEDMARK for commercial use – meaning using the drug substances to make drug products – at another facility.²⁹ And because “NDA submissions require ... long-term manufacturing stability data (up to 6 months),” Fennec also knew or should have known that it had “to show that [any] new manufacturing facility can produce a stable commercial batch of Pedmark.”³⁰

84. But Fennec did not have the required long-term manufacturing stability data at the time it initiated its rolling NDA of PEDMARK. Nor did it know when it would be able to obtain such data because Avista was in the process of being acquired by Cambrex.

²⁹ See *Overview of Durham, NC, USA Facility*, CAMBREX CORP., <https://www.cambrex.com/facilities/durham-nc-usa/> (last visited Jan. 29, 2021); *Overview of Longmont, CO, USA Facility*, CAMBREX CORP., <https://www.cambrex.com/facilities/longmont-co-usa/> (last visited Jan. 29, 2021); *Overview of Agawam, MA, USA Facility*, CAMBREX CORP., <https://www.cambrex.com/facilities/agawam-ma-usa/> (last visited Jan. 29, 2021); *Overview of Edinburgh, UK Facility*, CAMBREX CORP., <https://www.cambrex.com/facilities/edinburgh-uk/> (last visited Jan. 29, 2021).

³⁰ Deniel Mero, *Fennec Delays NDA Due to Manufacturing Facility Change*, PROPTHINK (Mar. 13, 2019 11:48 AM), <https://propthink.com/fennec-delays-nda-due-to-manufacturing-facility-change/#>.

This acquisition was publicly announced in November 2018³¹ and completed in January 2019.³² Simply put, for all these reasons, Fennec did not have a reasonable basis for targeting the second half of 2019 for FDA approval of PEDMARK, despite what it told investors.

85. But it was not until March 13, 2019 that investors learned what Fennec already knew or should have known by December 20, 2018 which is that “a site transition for the commercial manufacturing site” of PEDMARK was required and that transition would delay the Company’s full submission to the FDA by at least six months, and the commercial launch by at least a year. Fennec, however, falsely blamed the site change on “the drug substance manufacturer for PEDMARK™ [being] recently acquired,” and assured investors that “the acquiring company has large scale commercial capabilities and a proven and extensive track record of successful FDA inspections and product launches.”

86. As the Triangle Business Journal reported on April 25, 2019, “according to [Fennec’s] CFO Robert Andrade, the FDA process was delayed because the third-party manufacturer the company is using was acquired, meaning their drug would be produced

³¹ *Cambrex to Acquire Avista Pharma Solutions, Adding Early Stage API and Finished Dosage Form Development & Testing Services to its Global Contract Development & Manufacturing Network*, CAMBREX CORP. (Nov. 20, 2018), <https://www.cambrex.com/cambrex-to-acquire-avista-pharma-solutions-adding-early-stage-api-and-finished-dosage-form-development-testing-services-to-its-global-contract-development-manufacturing-network/>.

³² *Cambrex Completes Acquisition of Avista Pharma Solutions*, CAMBREX CORP. (Jan. 2, 2019), <https://www.cambrex.com/cambrex-completes-acquisition-of-avista-pharma-solutions/>.

in a different facility – so it needed a review batch from the new facility.”³³

87. Conveniently, just over a month *before* announcing the manufacturing site change and delay in the commercial launch of PEDMARK, Defendants were able to secure a \$12.5 million senior debt facility with a maturity date of October 1, 2023 from the Bridge Bank which was to be funded upon NDA approval. The Company intended to use the proceeds from the loan for commercialization activities after NDA approval.

88. Finally, despite the year delay in the commercial launch of Fennec’s only lead drug candidate and the “steady drop in stock value from \$14.07 a share in April 2018 to trading around \$4.40” in April 2019, Defendants Raykov and Andrade received raises of about 15% in April 2019, “continuing their compensation’s steady increase since starting with the company.”³⁴ Raykov’s base salary was increased from \$350,000 to \$400,000 and Andrade’s from \$250,000 to \$290,000.

2. *Unbeknownst to investors, there was a high risk that Fennec’s drug product manufacturer would not pass FDA inspections, which would further delay FDA approval of PEDMARK.*

89. Fennec’s disclosures to investors confirm that Defendants knew that a successful inspection of its product manufacturing processes was critical to obtaining FDA approval. Nonetheless, despite leading investors to believe that it would receive FDA

³³ Seth Thomas Gulledge, *This \$90M public company is “set up” for sale, CFO says*, AMERICAN CITY BUSINESS JOURNALS (Apr. 25, 2019 2:30 PM EDT), <https://www.bizjournals.com/triangle/news/2019/04/25/this-90m-public-company-is-set-up-for-sale-cfo.html>.

³⁴ Seth Thomas Gulledge, *With stock down 68% in past year, RTP outfit’s CEO, CFO enjoy 15% bump in compensation*, AMERICAN CITY BUSINESS JOURNALS (Apr. 24, 2019 2:08 PM EDT), <https://www.bizjournals.com/triangle/news/2019/04/24/with-stock-down-68-in-past-year-rtp-outfits-ceo.html>.

approval for PEDMARK in August 2020, Defendants either failed to conduct adequate due diligence into Fennec's third-party product manufacturer or, even worse, ignored the fact that its chosen manufacturer would likely not pass a pre-approval inspection (PAI). Either way, none of this was disclosed to investors, and as a result, Fennec's stock plummeted in August 2020 when investors finally learned that manufacturing issues *again* delayed approval of PEDMARK – a drug which still has not received FDA approval.

a. Manufacturing according to cGMP standards is a critical component of gaining FDA approval.

90. Obtaining regulatory approval (by the FDA) for new drugs is essential for any company (such as Fennec) seeking to market a new drug in the United States. Simply put, manufacturing issues found during the FDA's PAI will cause a delay in FDA approval, which will, in turn, negatively impact a company's expected sales and, if investors are caught unaware, the company's stock price.

91. The problem of manufacturing is further complicated when a drug company, such as Fennec, outsources manufacturing to a third-party. The drug sponsor must then rely on the manufacturer for quality assurance and cGMP.

92. Further compounding the issue for Fennec is the fact that manufacturers of sterile parenteral products, such as PEDMARK, are typically more complex than those required for the production of other products, such as oral dosage forms. The stability of parenteral solutions must be assured. The product must be sufficiently stable to remain in solution (or within the freeze-dried cake) for a reasonable amount of time. Therefore, sterile parental products require heightened testing of product packaging, transportation and

storage. All of these issues relate directly to product quality; thus, a culture of quality and effective quality systems is essential for successful manufacturing of complex products such as sterile injectables. As the drug sponsor, Fennec is responsible for ensuring that any and all third-party manufacturers of PEDMARK possesses the necessary knowledge, capability, and experience to successfully produce this complex drug.

93. Accordingly, in order to make assurances to investors as to when and whether PEDMARK would receive FDA approval, Fennec needed to be hyper-sensitive to quality control and manufacturing issues with any third-party manufacturer with whom it chose to contract to make its drug. The failure to do sufficient due diligence into a third-party manufacturer or double-check the reliability of the manufacturing facility would have been material to any investor's decision as to whether and how long to invest in Fennec because failing to detect and remedy deficiencies prior to the FDA's PAI will dramatically and materially delays a drug's approval.

94. So important are the FDA's pre-approval inspections, that as a former Quality Assurance Director at the Longmont Site from June 2015 to July 2019 noted, pharmaceutical companies typically hold a mock inspection of the facilities manufacturing their drug(s) prior to the PAI to try to identify any deficiencies.

b. Fennec failed to ensure that its manufacturer would be able to successfully produce PEDMARK under cGMP standards.

95. In February 2020, Fennec announced the completion of the Rolling Review of the PEDMARK NDA submission and that it was eligible for Priority Review because the FDA granted PEDMARK Orphan Drug, Breakthrough Therapy, and Fast Track

designations.³⁵ If granted Priority Review, the PDUFA action date was expected in the third quarter of 2020 (“3Q20”).

96. In April 2020, Fennec announced that the FDA had accepted the PEDMARK NDA for filing, granted Priority Review which “shorten[ed] the review period from the standard ten months to six months from the submission of the NDA,” and “set a [PDUFA] target action date of August 10, 2020 for the completion of [the] FDA’s review.”³⁶ Defendant Raykov noted that “[t]he FDA filing acceptance of our NDA and granting of Priority Review represents a *significant milestone* in the development of PEDMARK and we look forward to *working closely* with the Agency during this review process.”

97. After the FDA accepted the PEDMARK NDA, Defendants knew or should have known that the FDA would conduct a PAI of the drug product manufacturing facility well in advance of the PDUFA date. Accordingly, as described above, if they had not already, Defendants *should* have conducted due diligence and/or a deep-dive quality audit of the drug product manufacturing facility to ensure that it would pass the inspection. If Fennec chose not to do the required due diligence, it should have disclosed this fact to investors, as it understandably would have been critical to investors’ decisions as to

³⁵ *Fennec Pharmaceuticals Completes Rolling Submission of New Drug Application (NDA) to U.S. Food and Drug Administration For PEDMARK™ and Also Submits Marketing Authorization Application (Maa) to European Medicines Agency*, FENNEC PHARMACEUTICALS, INC. (Feb. 11, 2020) <https://investors.fennecpharma.com/news-releases/news-release-details/fennec-pharmaceuticals-completes-rolling-submission-new-drug>.

³⁶ *Fennec Pharmaceuticals Announces FDA Filing Acceptance and Priority Review of New Drug Application For PEDMARK™*, FENNEC PHARMACEUTICALS, INC. (Apr. 13, 2020), <https://investors.fennecpharma.com/news-releases/news-release-details/fennec-pharmaceuticals-announces-fda-filing-acceptance-and>.

whether or not to purchase and/or to sell the stock.

98. Instead of focusing on conducting due diligence, a quality audit and/or a mock inspection of its product manufacturer's facility to ensure FDA approval of its only drug, Fennec was focused on selling the Company. Fennec executives stated in April 2019 that the Company was "set up for the potential – and expectation – of buyout scenarios" so "[w]ho undergoes those commercialization efforts ... remain[ed] to be seen."³⁷ As Defendant Andrade noted, "[w]e can't say, per [se], when or if we're going to get sold, but certainly we are set up for that potential ... obviously you can see how we're set up right now. . . . We don't have a lot of employees, we don't have leases, we don't have anything really in the company. We have a great asset in a drug and a great team." Andrade further explained that this "'lean and mean' structure compliment[ed] a tight financial strategy" which "rais[ed] only enough capital to reach milestones and kept nearly all of their deals non-dilutive," and as a result, "[w]e've had a lot of interest historically from potential partners" and "[w]e anticipate as we get closer to approval and to the extent we launch the drug ourselves that will continue to be one of the activities around the company."

99. Since Defendants did not ensure that Fennec's product manufacturer met cGMP standards prior to the PAI, the FDA observed numerous deficiencies during its inspection of the manufacturing facility which were discussed with management of Fennec and its manufacturer during and at the conclusion of the inspection. As the former Senior Director of Avista explained, a pharmaceutical company would know before receiving a

³⁷ *Id.* at n.33.

CRL what deficiencies the FDA found at the manufacturing site *via* the exit interview with the PAI inspector and the Form 483 subsequently issued in relation to the PAI.

100. As a result, instead of announcing FDA approval on August 11, 2020, as investors expected, Fennec announced it had received a CRL the day before.³⁸ According to the CRL, which has not been publicly released, the FDA had identified deficiencies resulting in a Form 483, listing conditions or practices requiring resolution prior to PEDMARK's approval, after recently completing a pre-approval inspection of the product manufacturer's production facility. That morning, "Fennec management hosted a call to discuss the FDA rejection. . . . [M]anagement disclosed that the issue impacted the manufacturing facility as a whole, not only Fennec."³⁹

101. Because the deficiencies identified by the FDA impacted the drug product manufacturing facility as a whole, such deficiencies would have been uncovered had Fennec conducted the necessary due diligence, a quality audit and/or a mock inspection of the facility. In short, *either* Fennec had knowledge of such deficiencies and recklessly disregarded them without disclosing them to investors, possibly due to the fact that Fennec was being prepared for sale, *or* recklessly failed to discover these deficiencies prior to the FDA inspection. Moreover, after knowing that the FDA issued its product manufacturer a

³⁸ *Fennec Pharmaceuticals Receives Complete Response Letter From the FDA For Its New Drug Application For Pedmark™ To Prevent Ototoxicity Associated With Cisplatin In Pediatric Patients With Localized, Non-Metastatic, Solid Tumors*, FENNEC PHARMACEUTICALS, INC. (Aug. 11, 2020), <https://investors.fennecpharma.com/news-releases/news-release-details/fennec-pharmaceuticals-receives-complete-response-letter-fda-its>.

³⁹ Deniel Mero, *Manufacturing Issue Leads to Fennec CRL*, PROPTHINK (Aug. 11, 2020 4:14 PM), <https://propthink.com/manufacturing-issue-leads-to-fennec-crl/>.

Form 483 listing serious deficiencies observed during the pre-approval inspection, Fennec failed to disclose those deficiencies to investors until it received the CRL.

- c. *Fennec's most likely choice of manufacturer had serious prior issues with passing FDA inspections and had not previously produced PEDMARK; that risk was not disclosed to investors.*

102. Defendants still have not disclosed the identity of Fennec's drug product manufacturer, thus leaving investors guessing at who the likely manufacturer is.⁴⁰ Nonetheless, Plaintiff's investigation has uncovered which manufacturers most likely were contracted to produce PEDMARK by Fennec, and both of those manufacturers had serious, prior issues with FDA inspections and neither had produced PEDMARK previously.

103. The FDA has inspected, found deficiencies, and issued a Form 483 to two companies in 2020 that have the ability to commercially manufacture PEDMARK. Because both of those companies had prior issues with FDA inspections and neither had previously manufactured PEDMARK for the clinical trials, there was a materially higher risk of their facilities not passing the PAI. But that risk was not disclosed to investors.

104. *First*, Pharmaceuticals International, Inc. ("PII"), a contract development and manufacturing organization ("CDMO"), with facilities in Hunt Valley, MD dedicated manufacturing suites for injectables ("PII Facilities"),⁴¹ received a Form 483 for

⁴⁰ Plaintiff has filed a Freedom of Information Act (FOIA) request with the FDA seeking information related to Fennec's manufacturers. In the event Plaintiff receives information from the FDA that is pertinent to this action, Plaintiff reserves the right to amend this complaint.

⁴¹ About Us, PHARMACEUTICALS INTERNATIONAL, INC., <https://www.pharm-int.com/about-us/> (last visited Jan. 29, 2021).

deficiencies from an inspection which took place July 6-10, 2020.⁴² The deficiencies highlighted by the FDA included:

- Reports of analysis from component suppliers were accepted in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.
- Buildings used in the manufacture, processing, packing, or holding of a drug product did not have the suitable construction to facilitate cleaning, maintenance, and proper operations.
- Equipment and utensils were not maintained at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.
- Procedures designed to prevent microbiological contamination of drug products purporting to be sterile were not established.
- Equipment for adequate control over micro-organisms was not provided when appropriate for the manufacture, processing, packing or holding of a drug product.⁴³

105. PII has a documented history of receiving a Form 483 nearly every year for the past decade, specifically for prior inspections of PII Facilities ending on November 9, 2018, November 16, 2017, October 27, 2017, March 24, 2017, April 4, 2016, March 18, 2016, May 29, 2015, May 22, 2015, April 14, 2015, July 17, 2014, September 13, 2013, May 22, 2013, October 22, 2012, May 25, 2011, December 16, 2010, and July 29, 2009.

106. If PII is Fennec's drug product manufacturer, Defendants knew or should

⁴² Robert Martin FDA, Edmund Mrak FDA, *483 Pharmaceuticals International Jul 2020* (July 10, 2020), <https://fdazilla.com/store/form483/1000513101-20200710>.

⁴³ U.S. FOOD & DRUG ADMIN., INSPECTION CITATION (Dec. 23, 2020), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-citation>.

have known about the deficiencies previously identified by the FDA at PII Facilities through publicly available sources like the FDA's website. This risk, together with the name of the manufacturer, should have been disclosed to investors.

107. Second, Bayer AG ("Bayer"), a global pharmaceutical company which manufactures drug products out of its headquarters in Leverkusen, Germany ("Leverkusen Site"), received a Form 483 from an inspection that took place July 20-27, 2020.⁴⁴ The deficiencies highlighted by the FDA included:

- Control procedures were not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.
- Laboratory controls did not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.
- Written procedures for cleaning and maintenance failed to include description in sufficient detail of methods, equipment and materials used.
- Written records of investigations into unexplained discrepancies did not always include the conclusions and follow-up.
- There was insufficient physical or spatial separation from operations and other drug products to prevent mix-ups and cross-contamination.⁴⁵

108. Not only had Bayer previously received a Form 483, but the deficiencies raised therein escalated into a warning letter from the FDA on November 14, 2017, after

⁴⁴ Michael Charles FDA, Wayne Mcgrath FDA, *483 Bayer AG Jul 2020* (July 27, 2020), <https://fdazilla.com/store/form483/3002806462-20200727>.

⁴⁵ *Id.* at n.43.

an inspection of the Leverkusen Site that had taken place January 12-27, 2017.⁴⁶ Bayer had also received a Form 483 from other inspections of the Leverkusen Site which had ended on March 22, 2019, July 9, 2012, and February 23, 2010.

109. If Bayer was Fennec's product manufacturer, Defendants knew or should have known about the deficiencies previously identified by the FDA at the Leverkusen Site not only through publicly available sources like the FDA's website, but through its Chief Commercial Officer, Shubh Goel, who had previously served as Head of Global Launch Team at Bayer. This risk should have also been disclosed to investors.

110. Because Defendants did not disclose the identity of Fennec's product manufacturer and/or other material facts about that manufacturer's prior issues with FDA inspections and/or commercial product launches, and instead touted the Company's successful manufacturing and preparedness for the commercial launch of PEDMARK, investors had no reason to expect a CRL and a second delay in the launch due to manufacturing deficiencies.

V. FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD⁴⁷

111. The Class Period begins on December 20, 2018 when Fennec issued a press release before markets opened announcing it "has initiated a rolling New Drug Application (NDA) for PEDMARKTM (a unique formulation of sodium thiosulfate (STS) to be

⁴⁶ Justin Boyd FDA, *483 Bayer AG Jan 2017* (Jan. 20, 2017), <https://fdazilla.com/store/form483/3002806462-20170120>.

⁴⁷ The particular portions of the statements alleged to be false or misleading are in bold and italicized herein.

administered by infusion) for the prevention of ototoxicity induced by cisplatin chemotherapy in patients 1 month to < 18 years of age with localized, non-metastatic, solid tumors. *The Company is targeting U.S. approval of PEDMARK™ in the second half of 2019.*” On this news, Fennec’s stock price increased nearly 20% on heavy trading to close at \$6.43 on December 20, 2018.

112. The statements contained in ¶ 111 *supra* were materially false and misleading because Defendants knew, or recklessly disregarded, the fact that because Fennec’s drug substance manufacturer was in the process of being acquired and that manufacturer’s facility did not have large scale commercial capabilities or a proven and extensive track record of successful FDA inspections and product launches, the Company’s commercial manufacturing site would need to be changed and thus the Company could not possibly achieve approval of PEDMARK in the second half of 2019.

113. Then, before markets opened on March 13, 2019, Fennec issued a press release providing a business update and announcing fiscal year 2018 (“FY2018”) financial results. Despite announcing a minimum six-month delay in the full submission to the FDA, and as a result, the delayed commercialization of PEDMARK because “the drug substance manufacturer for PEDMARK™ [being] recently acquired requiring a site transition for the commercial manufacturing site,” the Company assured investors that:

The *new facility* of the acquiring company *has large scale commercial capabilities and a proven and extensive track record of successful FDA inspections and product launches*. As such, full submission is targeted for late 2019 to early 2020. If approved, *Fennec expects a first commercial launch for PEDMARK in the second half of 2020*.

114. The statements contained in ¶ 113 *supra* were materially false and misleading

because Defendants knew, or recklessly disregarded, that: despite a delayed commercial launch resulting from their failure to conduct sufficient due diligence to ensure that the substance manufacturing site would not need to change: (i) Defendants failed to conduct adequate due diligence into Fennec's product manufacturer to ensure that it complied with cGMP or Defendants ignored red flags indicating that the product manufacturing site would not pass a pre-approval inspection because it was not in compliance with cGMP, unlike the substance manufacturer; (ii) as a result, the FDA would, and did, observe deficiencies at the product manufacturing site warranting a Form 483 and the denial of Fennec's NDA for PEDMARK; and (iii) as a result, Fennec did not have a reasonable basis for expecting a commercial launch of PEDMARK in the second half of 2020. To date, the FDA has still not approved, and the Company has still not commercially launched PEDMARK.

115. On March 15, 2019, Fennec filed its annual report for FY2018 ("2018 10-K") with the SEC which was signed by Defendant Raykov, as appointed and executed by Defendants Andrade, Haigh, Islam, Rallis and Brughera as their attorney-in-fact and agent with power of substitution. The 2018 10-K warned that:

We and our third-party manufacturers are also required to comply with the applicable current FDA Good Manufacturing Practices regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, manufacturing facilities must be approved by the FDA before they can be used to manufacture our product, and they are subject to additional FDA inspection. ***If we fail to comply with any of the FDA's continuing regulations, we could be subject to reputational harm and sanctions, including:***

- ***delays, warning letters and fines;***
- product recalls or seizures and injunctions on sales;

- refusal of the FDA to review pending applications;
- total or partial suspension of production;
- withdrawals of previously approved marketing applications; and
- civil penalties and criminal prosecutions.

116. In addition, the 2018 10-K warned that “[o]ur product candidates could fail to receive marketing approval for many reasons, including the following ... *the FDA or comparable foreign regulatory authorities may find inadequate the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies.*”

117. The statements contained in ¶¶ 115-116 *supra* were materially false and misleading because Defendants knew, or recklessly disregarded the fact that, that: these risks had already materialized at the start of the Class Period because Defendants had failed to conduct adequate due diligence into Fennec’s third-party product manufacturer to ensure that it complied with cGMP or, at minimum, Defendants ignored red flags indicating that the product manufacturing site would likely not pass a pre-approval inspection because it was not in compliance with cGMP and, as a result, the FDA would, and did, observe deficiencies at the manufacturing site warranting a Form 483 and the denial of the Company’s NDA for PEDMARK. To date, the Company has still not confirmed when it will resubmit the NDA and the FDA has still not approved PEDMARK.

118. Additionally, the 2018 10-K included certifications under Section 302 of the Sarbanes-Oxley Act of 2002 (“SOX”) by Defendants Raykov and Andrade attesting, in relevant part, that “[b]ased on my knowledge, this Annual Report does not contain any untrue statement of a material fact or *omit to state a material fact necessary to make the*

statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report.”

119. The statements contained in ¶ 118 *supra* were materially false and misleading because Defendants knew, or recklessly disregarded, that: (i) they had failed to conduct adequate due diligence into Fennec’s third-party drug product manufacturer to ensure that it complied with cGMP or Defendants ignored red flags indicating that the product manufacturing site would likely not pass a pre-approval inspection because it was not in compliance with cGMP; (ii) as a result, the FDA would, and did, observe deficiencies at the manufacturing site warranting a Form 483 and the denial of the Company’s NDA or PEDMARK; and (iii) thus, the Company did not have a reasonable basis for a commercial launch of PEDMARK in the second half of 2020. To date, the FDA has still not approved, and the Company has still not commercially launched, PEDMARK.

120. On May 9, 2019, Fennec issued a press release providing a business update and announcing first quarter 2019 (“1Q19”) financial results.⁴⁸ The press release quotes Defendant Raykov as stating that “[w]e were very pleased with *the production transition of PEDMARK™ API to the new commercial drug substance manufacturing site during the first quarter.*”

121. By this point, as noted, the commercial launch of PEDMARK had been delayed because of Defendants’ failure to conduct sufficient due diligence to ensure that

⁴⁸ *Fennec Provides Business Update and Announces First Quarter 2019 Financial Results*, FENNEC PHARMACEUTICALS, INC. (May 9, 2019 6:00 AM ET), <https://www.globenewswire.com/news-release/2019/05/09/1820548/0/en/Fennec-Provides-Business-Update-and-Announces-First-Quarter-2019-Financial-Results.html>.

the *substance* manufacturing site would not need to change. Despite disclosing this delay due to the site transition, Defendants continued to fail to adequately monitor their manufacturers and to disclose that failure to investors. Specifically, the statements contained in ¶ 120 *supra* were materially false and misleading because Defendants knew, or recklessly disregarded the fact that: (i) Defendants did not conduct adequate due diligence into Fennec’s *product* manufacturer to ensure that it complied with cGMP or ignored red flags indicating that the product manufacturing site would not pass a pre-approval inspection because it was not in compliance with cGMP, unlike the substance manufacturer; and, (ii) as a result, the FDA would, and did, observe deficiencies at the product manufacturing site warranting a Form 483 and the denial of Fennec’s NDA for PEDMARK. In short, Fennec did not have a reasonable basis to tell investors that it expected a commercial launch of PEDMARK in the second half of 2020. To date, the FDA has still not approved, and the Company has still not commercially launched PEDMARK.

122. On August 9, 2019, Fennec issued a press release providing a business update and announcing second quarter 2019 (“2Q19”) financial results. The press release quotes Defendant Raykov as stating that “[d]uring the quarter, *we* are pleased to have *successfully manufactured PEDMARK and are working closely with the FDA on our rolling NDA submission*” and “*we plan to launch PEDMARK in the second half of 2020.*”

123. By this point, as noted, the commercial launch of PEDMARK had been delayed because of Defendants’ failure to conduct sufficient due diligence to ensure that the *substance* manufacturing site would not need to change. Despite disclosing this delay due to the site transition and updating investors as to the successful manufacturing of

PEDMARK, the Defendants continued to fail to adequately monitor their manufacturers and to disclose that failure to investors. Specifically, the statements contained in ¶ 122 *supra* were materially false and misleading because Defendants knew, or recklessly disregarded the fact that: (i) Defendants did not conduct adequate due diligence into Fennec’s *product* manufacturer to ensure that it complied with cGMP or ignored red flags indicating that the product manufacturing site would not pass a pre-approval inspection because it was not in compliance with cGMP, unlike the substance manufacturer; and, (ii) as a result, the FDA would, and did, observe deficiencies at the product manufacturing site warranting a Form 483 and the denial of Fennec’s NDA for PEDMARK. In short, Fennec did not have a reasonable basis to tell investors that it expected a commercial launch of PEDMARK in the second half of 2020. To date, the FDA has still not approved, and the Company has still not commercially launched PEDMARK.

124. On November 12, 2019, Fennec issued a press release providing a business update and announcing third quarter 2019 (“3Q19”) financial results. The press release quotes Defendant Raykov as stating that “*we are focused on building the necessary team and infrastructure to support a rapid commercial launch of PEDMARK*, if approved, in the second half of 2020.”

125. The statements contained in ¶ 124 *supra* were materially false and misleading because Defendants knew, or recklessly disregarded, that: (i) their focus on the “rapid commercial launch of PEDMARK” did not include adequate due diligence into Fennec’s product manufacturer to ensure that it complied with cGMP or ignored red flags indicating that the product manufacturing site would not pass a pre-approval inspection because it

was not in compliance with cGMP; (ii) as a result, the FDA would, and did, observe deficiencies at the product manufacturing site warranting a Form 483 and the denial of Fennec's NDA for PEDMARK; and (iii) thus, Fennec did not have a reasonable basis for a commercial launch of PEDMARK in the second half of 2020. To date, the FDA has still not approved, and the Company has still not commercially launched PEDMARK.

126. Before markets opened on February 11, 2020, Fennec issued a press release announcing the completion of its rolling NDA to the FDA for PEDMARK.⁴⁹ The press release quotes Defendant Raykov as stating that “[w]e are well underway with commercialization readiness activities to support the potential launch of PEDMARK and our transition to becoming a commercial-stage organization.” On this news, Fennec's stock price increased nearly 14% on heavy trading to close at \$7.55 on February 13, 2020.

127. The statements contained in ¶ 126 *supra* were materially false and misleading because Defendants knew, or recklessly disregarded, that: (i) their “commercialization readiness activities” did not include adequate due diligence into Fennec's product manufacturer to ensure that it complied with cGMP or ignored red flags indicating that the product manufacturing site would not be pass a pre-approval inspection because it was not in compliance with cGMP; (ii) as a result, the FDA would, and did, observe deficiencies at

⁴⁹ *Fennec Pharmaceuticals Completes Rolling Submission of New Drug Application (NDA) to U.S. Food and Drug Administration for PEDMARK™ and Also Submits Marketing Authorization Application (MAA) to European Medicines Agency, FENNEC PHARMACEUTICALS INC.* (Feb. 11, 2020 6:00 AM ET), <https://www.globenewswire.com/news-release/2020/02/11/1982856/0/en/Fennec-Pharmaceuticals-Completes-Rolling-Submission-of-New-Drug-Application-NDA-to-U-S-Food-and-Drug-Administration-for-PEDMARK-and-Also-Submits-Marketing-Authorization-Application.html>.

the product manufacturing site warranting a Form 483 and the denial of Fennec's NDA for PEDMARK; and (iii) thus, Fennec did not have a reasonable basis for a commercial launch of PEDMARK in the second half of 2020. To date, the FDA has still not approved, and the Company has still not commercially launched PEDMARK.

128. Before markets opened on February 14, 2020, Fennec issued a press release providing a business update and announcing fiscal year 2019 ("FY2019") financial results.⁵⁰ The press release quotes Defendant Raykov as stating that "*[d]uring the year, we also made solid progress in preparing for the potential launch of PEDMARK including the hiring of a chief commercial officer and the preparation and execution of our commercial readiness plan.*" On this news, Fennec's stock price increased over 7% on heavy trading to close at \$8.10 on February 20, 2020.

129. The statements contained in ¶ 128 *supra* were materially false and misleading because Defendants knew, or recklessly disregarded, that: (i) their "solid progress in preparing for the potential launch of PEDMARK ... and the preparation and execution of our commercial readiness plan" did not include adequate due diligence into Fennec's product manufacturer to ensure that it complied with cGMP or ignored red flags indicating that the product manufacturing site would not pass a pre-approval inspection because it was not in compliance with cGMP; (ii) as a result, the FDA would, and did, observe deficiencies at the product manufacturing site warranting a Form 483 and the denial of

⁵⁰ *Fennec Provides Business Update and Announces Fiscal Year 2019 Financial Results*, FENNEC PHARMACEUTICALS INC. (Feb. 14, 2020 6:00 AM ET), <https://www.globenewswire.com/news-release/2020/02/14/1985166/0/en/Fennec-Provides-Business-Update-and-Announces-Fiscal-Year-2019-Financial-Results.html>.

Fennec’s NDA for PEDMARK; and (iii) thus, Fennec did not have a reasonable basis for a commercial launch of PEDMARK in the second half of 2020. To date, the FDA has still not approved, and the Company has still not commercially launched PEDMARK.

130. Also on February 14, 2020, Fennec filed with the SEC its annual report for FY2019 (“2019 10-K”) signed by Defendant Raykov, as appointed and executed by Defendants Andrade, Haigh, Islam, Rallis, Brughera and Cook as their attorney-in-fact and agent with power of substitution. The 2019 10-K warned that:

We and our third-party manufacturers are also required to comply with the applicable current FDA Good Manufacturing Practices regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, manufacturing facilities, which we outsource to third parties, must be approved by the FDA before they can be used to manufacture our product, and they are subject to additional FDA inspection. *If we fail to comply with any of the FDA’s continuing regulations, we could be subject to reputational harm and sanctions, including:*

- *delays, warning letters and fines;*
- *product recalls or seizures and injunctions on sales;*
- *refusal of the FDA to review pending applications;*
- *total or partial suspension of production;*
- *withdrawals of previously approved marketing applications; and*
- *civil penalties and criminal prosecutions.*

131. In addition, the 2019 10-K warned that “[o]ur product candidate could fail to receive marketing approval for many reasons, including the following...*the FDA or comparable foreign regulatory authorities may find inadequate the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies.*”

132. The statements contained in ¶¶ 130-131 *supra* were materially false and misleading because Defendants knew, or recklessly disregarded the fact that: while the 10-

K portrayed these risks as risks that could evolve in the future, in fact, these risks had *already* materialized by the start of the Class Period because the Defendants had failed to conduct adequate due diligence into Fennec's third-party product manufacturer to ensure it complied with cGMP or ignored red flags indicating that the product manufacturing site would likely not pass a pre-approval inspection because it was not in compliance with cGMP and, as a result, the FDA would, and did, observe deficiencies at the product manufacturing site warranting a Form 483 and the denial of PEDMARK's NDA. To date, the Company has still not confirmed when it will resubmit the NDA and the FDA has still not approved PEDMARK.

133. Additionally, the 2019 10-K included SOX certifications under Section 302 by Defendants Raykov and Andrade attesting, in relevant part, that “[b]ased on my knowledge, this Annual Report does not contain any untrue statement of a material fact or *omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading* with respect to the period covered by this Annual Report.”

134. The statements contained in ¶ 133 *supra* were materially false and misleading because Defendants knew, or recklessly disregarded, that: (i) they had failed to conduct adequate due diligence into Fennec's third-party product manufacturer to ensure that it complied with cGMP or were ignoring red flags indicating that the product manufacturing site would likely not pass a pre-approval inspection because it was not in compliance with cGMP; (ii) as a result, the FDA would, and did, observe deficiencies at the manufacturing site warranting a Form 483 and the denial of the Company's NDA or PEDMARK; and (iii)

thus, the Company did not have a reasonable basis for a commercial launch of PEDMARK in the second half of 2020. To date, the FDA has still not approved, and the Company has still not commercially launched PEDMARK.

135. Before markets opened on April 13, 2020, Fennec issued a press release announcing that the FDA had accepted for filing and granted Priority Review for the PEDMARK NDA. The press release quotes Defendant Raykov as stating that “[t]he *FDA filing acceptance of our NDA and granting of Priority Review represents a significant milestone in the development of PEDMARK* and we look forward to working closely with the Agency during this review process.” On this news, Fennec’s stock price increased nearly 12% on heavy trading to close at \$7.23 on April 13, 2020.

136. The statements contained in ¶ 135 *supra* were materially false and misleading because Defendants knew, or recklessly disregarded the fact that: the risk of the FDA denying the PEDMARK NDA was high despite the FDA filing acceptance and granting of Priority Review because Defendants had failed to conduct adequate due diligence into Fennec’s third-party product manufacturer to ensure it complied with cGMP or ignored red flags indicating that the product manufacturing site would likely not pass a pre-approval inspection because it was not in compliance with cGMP and, as a result, the FDA would, and did, observe deficiencies at the product manufacturing site warranting a Form 483 and the denial of PEDMARK’s NDA. To date, the Company has still not confirmed when it will resubmit the NDA and the FDA has still not approved PEDMARK.

137. Before markets opened on May 14, 2020, Fennec issued a press release providing a business update and announcing first quarter 2020 (“1Q20”) financial results.

The press release quotes Defendant Raykov as stating that “*we continue to make progress on our commercial readiness plan in preparation for the potential launch of PEDMARK, if approved, in the second half of 2020.*” On this news, Fennec’s stock price increased over 5% on heavy trading to close at \$7.46 on May 18, 2020.

138. The statements contained in ¶ 137 *supra* were materially false and misleading because Defendants knew, or recklessly disregarded the fact that: (i) their “progress on our commercial readiness plan” did not include adequate due diligence into Fennec’s product manufacturer to ensure that it complied with cGMP or ignored red flags indicating that the product manufacturing site would not pass a pre-approval inspection because it was not in compliance with cGMP; (ii) as a result, the FDA would, and did, observe deficiencies at the product manufacturing site warranting a Form 483 and the denial of Fennec’s NDA for PEDMARK; and (iii) thus, Fennec did not have a reasonable basis for a commercial launch of PEDMARK in the second half of 2020. To date, the FDA has still not approved, and the Company has still not commercially launched PEDMARK.

139. On August 5, 2020, Fennec issued a press release providing a business update and announcing second quarter 2020 (“2Q20”) financial results. The press release quotes Defendant Raykov as stating that “[w]e continue to work with the FDA as a part of their review process in advance of the pending PEDMARKTM PDUFA date of August 10” and “[o]ur organization and commercial team have been actively preparing for launch readiness, and, as we await the FDA’s decision, we believe that *we are well positioned to commercialize PEDMARK, if approved, during the third quarter of 2020.*”

140. The statements contained in ¶ 139 *supra* were materially false and misleading

because Defendants knew, or recklessly disregarded the fact that: despite “continuing to work with the FDA as part of their review process in advance of the ... PDUFA date:” (i) their “active[] prepar[ation] for launch readiness” did not include adequate due diligence into Fennec’s product manufacturer to ensure that it complied with cGMP, or the Company ignored red flags indicating that the product manufacturing site would not pass a pre-approval inspection because it was not in compliance with cGMP; (ii) as a result of these failures, the FDA observed deficiencies at the product manufacturing site warranting a Form 483 and the denial of Fennec’s NDA for PEDMARK; and (iii) in short, Fennec did not have a reasonable basis for a commercial launch of PEDMARK during the third quarter of 2020. To date, the FDA has still not approved, and the Company has still not commercially launched PEDMARK.

VI. LOSS CAUSATION

141. The two declines in Fennec’s share price during the Class Period as alleged herein are actionable. The timing and magnitude of the Company’s share price declines on each of those days negates any inference that the losses suffered by Lead Plaintiff and the Class was caused by changed market conditions, macroeconomic or industry factors or Fennec-specific facts unrelated to Fennec and the Individual Defendants’ fraudulent conduct. The economic loss, *i.e.*, damages, suffered by Plaintiff and other Class members was a direct result of Fennec and the Individual Defendants’ fraudulent statements and the corresponding artificial inflation in Fennec’s securities prices and the subsequent significant decline in the value of Fennec’s securities when Fennec and the Individual Defendants’ prior acts of misconduct were revealed.

142. At all relevant times, Fennec and the Individual Defendants' materially false and misleading statements or omissions alleged herein directly or proximately caused the damages suffered by the Plaintiff and the putative Class. Those statements were materially false and misleading due to their failure to disclose a true and accurate picture of Fennec's ability to commercially manufacture PEDMARK. Throughout the Class Period, Defendants publicly issued materially false and misleading statements and omitted material facts necessary to make Defendants' statements not false or misleading, causing Fennec securities to be artificially inflated. Plaintiff and other Class members purchased and/or acquired Fennec securities at those artificially inflated prices, causing them to suffer the damages complained of herein.

143. Fennec and the Individual Defendants were deliberately reckless in not knowing or turning a blind eye to the fact that the Company's business model was not sustainable as it was struggling to compete for advertisers. Nonetheless, Fennec and the Individual Defendants made materially false and misleading public statements that provided false information to investors about the Company's ability to commercially manufacture PEDMARK. Thus, shares of the Company's securities continued to trade at levels artificially inflated by Fennec and the Individual Defendants' misleading justifications for the negative information was revealed on March 13, 2019 which maintained the artificial inflation in the Company's share price until it was fully removed on August 11, 2020.

Fennec's March 13, 2019 Partial Disclosure

144. Before the markets opened on March 13, 2019, Fennec issued a press release

providing a business update and announcing FY18 financial results. Fennec surprised investors by announcing that the Company had “notified the FDA that the drug substance manufacturer for PEDMARK™ was recently acquired requiring a site transition for the commercial manufacturing site. . . . As such, full submission is targeted for late 2019 to early 2020. If approved, Fennec expects a first commercial launch for PEDMARK™ in the second half of 2020.” Despite the delay, Fennec assured investors that “[t]he new facility of the acquiring company has large scale commercial capabilities and a proven and extensive track record of successful FDA inspections and product launches.” On this news, because of this lengthy delay (which obviously impacted projected drug sales and target revenues) the Company’s stock price fell over 14% to close at \$5.83 on March 14, 2019, after two days of heavy trading.

145. As SeekingAlpha noted in an article titled “Fennec Pharma down 9% on Pedmark filing delay” on March 13, 2019 that the Company’s stock price was “down on more than 70% higher volume ... in apparent response to its announcement that it now expects to complete the rolling submission of its U.S. marketing application for lead candidate PEDMARK near year-end or early 2020, a delay of six months or more.”⁵¹ Fennec “had already started the process, but its contract ingredient manufacturer was acquired which necessitated a facility change.”

⁵¹ Douglas W. House, *Fennec Pharma down 9% on PEDMARK filing delay*, SEEKING ALPHA (Mar. 13, 2019 12:31 PM ET), <https://seekingalpha.com/news/3442370-fennec-pharma-down-9-on-pedmark-filing-delay>.

Fennec's August 11, 2020 Class Period Ending Disclosure

146. Before the markets opened on August 11, 2020, Fennec issued a press release announcing receipt of a CRL the prior day from the FDA in which “the FDA identified deficiencies resulting in a Form 483, which is a list of conditions or practices that are required to be resolved prior to the approval of PEDMARK™.” That morning, “Fennec management hosted a call to discuss the FDA rejection. It was disclosed that the FDA found deficiencies during the pre-approval inspection of the manufacturing facility. This resulted in a Form 483. The FDA generally will issue a Form 483 if it finds issues with respect to the manufacturing procedure & cGMP standards.”⁵² Further, “FENC management disclosed that the issue impacted the manufacturing facility as a whole, not only Fennec.” As noted by PropThink, “[t]his is the second time that manufacturing issues have pushed back potential approval. We think *submission* will be delayed **at least** 6 months, which means that an *approval* decision will be delayed at least 12 months.” (italics and bold in original).

147. Wedbush analyst David Nierengarten similarly incorporated a preliminary approval delay of about 10 months, or to mid-2021, and lowered Fennec’s price target to \$11 from \$18 “[g]iven uncertainty around when the company will next engage with the FDA, what specific conditions will need to be satisfied at the manufacturing facility, and how long it will take to satisfy them.”⁵³

⁵² *Id.* at n.39.

⁵³ *Fennec price target lowered to \$11 from \$18 at Wedbush*, The Fly (Aug. 12, 2020), <https://thefly.com/news.php?symbol=FENC>.

148. On this news, the Company's stock price plummeted over **44%** to close at \$5.67 on August 13, 2020, after three days of heavy trading.

149. On August 11, 2020, SeekingAlpha published an article titled "Fennec Pharma craters on FDA rejection of Pedmark application" confirming that "[t]hinly traded micro cap Fennec" was "slump[ing] 32% premarket ... in response to its announcement that it received" a CRL "cit[ing] deficiencies at its manufacturing facility" for PEDMARK.⁵⁴

150. SeekingAlpha published another article on November 5, 2020 noting that Fennec's stock price had "tanked in August [2020] on the back of the FDA Complete Response Letter it received for Pedmark. This was critical for FENC, as shares were trading at all-time highs in anticipation for the FDA approval."⁵⁵ The article highlighted that:

The issues identified by the FDA . . . were related to the manufacturing facility for the drug, which is concerning. We firmly believe that these risks will create further value erosion to shareholders, due to costs associated with re-fitting of facilities, revenue setbacks and additional oversight from the FDA. What's more, **there's been little to no transparency from management on resolving this issue to date.**

151. Not until November 16, 2020 did Fennec issue a press release revealing that it had to have a "Type A meeting with the FDA to discuss the path forward for

⁵⁴ Douglas W. House, *Fennec Pharma craters on FDA rejection of Pedmark application*, SEEKING ALPHA (Aug. 11, 2020 6:34 AM ET), <https://seekingalpha.com/news/3603898-fennec-pharma-craters-on-fda-rejection-of-pedmark-application>.

⁵⁵ Zach Bristow, *Fennec Pharmaceuticals: The Compensation Is What's Missing*, SEEKING ALPHA (Nov. 5, 2020 11:17 AM ET), <https://seekingalpha.com/article/4385272-fennec-pharmaceuticals-compensation-is-missing>.

resubmission” of the NDA for PEDMARK⁵⁶ and to increase its R&D expenses for the quarter “due to an increase in R&D expenses after the Complete Response Letter.”⁵⁷ Fennec further stated that it was “working closely with the FDA and [its] third-party drug product manufacturer to fully address the CRL and plan[ned] to resubmit the NDA for PEDMARK™ with the goal of achieving regulatory approval and making PEDMARK™ commercially available to patients in need as quickly as possible.”

152. In its third-quarter 2020 Form 10-Q also filed that day, Fennec confirmed that it did “not believe it will receive FDA approval by December 31, 2020,” that its R&D expenses increased by \$573,000 “over the same period in 2019 as the Company’s activities increased after the CRL from the FDA related to manufacturing and regulatory,” and that it was “working with our third-party drug product manufacturer to be ready for re-inspection by the FDA.”⁵⁸ Defendants did not provide any additional detail on the timing of a resubmission to the FDA or the what R&D Fennec had to do to address the FDA’s concerns in the CRL. To date, the FDA still has not approved PEDMARK.

⁵⁶ The goal of Type A meetings is to help a stalled product development program proceed, and such a meeting will occur within 30 days of the FDA receiving a written meeting request. Type A meetings include, *inter alia*, special protocol assessment meetings requested by sponsors after receipt of the FDA’s evaluation of protocols under the special protocol assessment procedures. See <https://www.fda.gov/media/72253/download>.

⁵⁷ *Fennec Pharmaceuticals Announces Third Quarter 2020 Financial Results and Provides Business Update*, FENNEC PHARMACEUTICALS INC. (Nov. 16, 2020), <https://investors.fennecpharma.com/news-releases/news-release-details/fennec-pharmaceuticals-announces-third-quarter-2020-financial>.

⁵⁸ Fennec Pharmaceuticals Inc., Quarterly Report (Form 10-Q) (Nov. 16, 2020), <https://investors.fennecpharma.com/sec-filings/sec-filing/10-q/0001104659-20-125638>.

VII. PRESUMPTION OF RELIANCE – FRAUD ON THE MARKET

153. Lead Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things: (a) Defendants made public misrepresentations or failed to disclose material facts; (b) the omissions and misrepresentations were material; (c) the Company's securities traded in an efficient market; (d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and (e) Lead Plaintiff and the other members of the Class purchased Fennec securities between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

154. At all relevant times, the market for Fennec's securities was efficient for the following reasons, among others: (a) Fennec's shares met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient market; (b) during the Class Period, shares of Fennec's securities were actively traded, demonstrating a strong presumption of efficiency; (c) Fennec was followed by securities analysts employed by brokerage firms who wrote reports about the Company which were distributed to their sales force and certain customers, were publicly available, and entered the public marketplace;⁵⁹ (d) as regulated issuer, Fennec filed periodic public reports with the SEC and/or NASDAQ; (e) Fennec regularly communicated with public investors, including through regular

⁵⁹ *Analyst Coverage*, FENNEC PHARMACEUTICALS, INC.
<https://investors.fennecpharma.com/index.php/financial-information/analyst-coverage>
(last visited Feb. 1, 2021).

disseminations of press releases on the major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and (f) unexpected material news about Fennec was rapidly reflected in and incorporated into Fennec's securities price during the Class Period.

155. As a result, the market for Fennec securities promptly digested current information regarding the Company from all publicly available sources and reflected such information in Fennec's share price. Under these circumstances, all purchasers or acquirers of Fennec's securities during the Class Period suffered similar injury through their purchase or acquisition of Fennec's securities at artificially inflated prices, and a presumption of reliance applies.

156. In addition, a Class-wide presumption of reliance is appropriate in this action under *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this Action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

VIII. INAPPLICABILITY OF SAFE HARBOR

157. The statutory safe harbor provided for forward-looking statements under

certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. All of the specific statements pleaded herein were not identified as, and/or were not “forward-looking statements” when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Fennec named under the Exchange Act who knew that those statements were materially false and misleading when made.

IX. CLASS ALLEGATIONS

158. Lead Plaintiff brings this Action as a class action, pursuant to Federal Rule of Civil Procedure 23(a) and 23(b)(3), on behalf of a class, consisting of all persons and entities that purchased, or otherwise acquired, Fennec securities during the Class Period, and were damaged by the conduct asserted herein. Defendants, the officers and directors of the Company, at all relevant times, and their immediate families and legal representatives, heirs, successors or assigns and any entity in which the Defendants named herein have, or had, a controlling interest, are excluded from the Class.

159. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial

benefits to the parties and the Court. Throughout the Class Period, Fennec's common shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Lead Plaintiff at this time, and can only be ascertained through appropriate discovery, Lead Plaintiff believes that there are hundreds, if not thousands, of members of the proposed Class. Millions of Fennec common stock were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Fennec or its transfer agent and may be notified of the pendency of this Action by mail, using the form of notice similar to that customarily used in securities class actions.

160. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to Class members that predominate over questions that may affect individual Class members include whether:

- (a) Defendants violated the federal securities laws;
- (b) Defendants omitted and/or misrepresented material facts;
- (c) Defendants' statements omitted material facts necessary to make the statements, in light of the circumstances under which they were made, not misleading;
- (d) The Company and the Individual Defendants with deliberate recklessness, disregarded or turned a blind eye toward the fact that their Class Period statements were false and misleading;
- (e) The price of Fennec securities was artificially inflated; and
- (f) The extent of damage sustained by Class members and the appropriate measure of damages.

161. Lead Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

162. Lead Plaintiff will fairly and adequately protect the interests of the Class members and has retained counsel who are experienced in securities class action litigation. Lead Plaintiff has no interests that conflict with those of the Class.

163. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. Lead Plaintiff knows of no difficulties in the management of this Action that would preclude its maintenance as a class action.

X. CLAIMS FOR RELIEF

COUNT I Violations of § 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against All Defendants)

164. Lead Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein. This claim is brought pursuant to § 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10(b)-5 promulgated thereunder, 17 C.F.R. § 240.10b-5, against Fennec and the Individual Defendants.

165. The Defendants in this Count, carried out a plan, scheme, and course of conduct which was intended to, and did: (i) deceive the investing public, including Lead

Plaintiff and the other Class members, as alleged herein; and (ii) cause Lead Plaintiff and the other members of the Class to purchase Fennec securities at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Fennec and the Individual Defendants took the actions set forth herein.

166. During the Class Period, Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Fennec's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

167. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Fennec's financial well-being and prospects, as specified herein.

168. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Fennec's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Fennec and its

business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

169. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these Defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these Defendants enjoyed significant personal contact and familiarity with the other Defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these Defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

170. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Those material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Fennec's financial well-being and prospects

from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

171. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Fennec's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Fennec's securities during the Class Period at artificially high prices and were damaged thereby.

172. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Fennec was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired

their Fennec securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

173. By virtue of the foregoing, Defendants violated Sections 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

174. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

COUNT II
Violations of § 20(a) of the Exchange Act
(Against the Individual Defendants)

175. Lead Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein. As members of Fennec's executive team and/or the Company's Board of Directors, the Individual Defendants acted as controlling persons of Fennec within the meaning of § 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

176. By virtue of their high-level positions, agency, ownership and contractual rights, and participation in and/or awareness of Fennec's operations and/or intimate knowledge of the false information filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of Fennec, including the content and dissemination of the various statements that Lead Plaintiff contends are false and misleading. The Individual Defendants were provided with, or had unlimited access to Fennec's reports, press releases, public filings and other statements, alleged by Lead Plaintiff to have been misleading, prior to and/or shortly after these

statements were issued and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

177. In particular, each of the Individual Defendants had direct and supervisory involvement in the day-to-day operation of the Company and, therefore, are presumed to have had the power to control and/or influence the particular transactions giving rise to the securities violations, as alleged herein, and exercised the same.

178. As set forth above, Fennec and the Individual Defendants each violated Sections 10(b) and Rule 10b-5, promulgated thereunder, by their acts and omissions as alleged in this Complaint and the Class was damaged thereby. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

179. As a direct and proximate result of the Individual Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their purchase or acquisition of Fennec securities during the Class Period.

XI. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff on behalf of himself and the Class, prays for relief and judgment, as follows:

a. Declaring this Action is a proper class action and certifying Lead Plaintiff as class representative pursuant to Rule 23(a) and Rule 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the Class defined herein and Lead Plaintiff's counsel as Class Counsel;

b. Awarding Lead Plaintiff and the other members of the Class compensatory

damages against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' conduct, in an amount to be proven at trial, including interest thereon;

c. Awarding Lead Plaintiff and the Class pre-judgment and post-judgment interest, as well as reasonable attorneys' fees, expert witness fees and other costs; and

d. Awarding such other equitable/injunctive or further relief as this Court may deem just and proper.

XII. JURY TRIAL DEMANDED

Lead Plaintiff hereby demands a trial by jury on all triable claims.

DATED: February 1, 2021

Respectfully Submitted,

COHEN MILSTEIN SELLERS & TOLL PLLC

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CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on February 1, 2021, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to counsel of record.

/s/ Ivy T. Ngo
Ivy T. Ngo